



**Australian Government**

**Department of Health  
and Aged Care**



# Schedule of Pharmaceutical Benefits

General Pharmaceutical Schedule - Volume 1

**Effective 1 April 2025**

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislation website at [www.legislation.gov.au](http://www.legislation.gov.au).

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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2025 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$8.67
	Dangerous drug fee	\$5.37
	Extemporaneously-prepared	\$10.71
	Allowable additional patient charge*	\$3.45
Additional Fees (for safety net prices):	Ready-prepared	\$1.45
	Extemporaneously-prepared	\$1.87
Patient Co-payments:	General	\$31.60
	Concessional	\$7.70
Safety Net Thresholds:	General	\$1694.00
	Concessional	\$277.20
Safety Net Card Issue Fee:		\$12.38

\* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 April 2025. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

## Prescriber Bag

### Deletions

#### Deletion – Item

13828T **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules (*pms-SALBUTAMOL*)

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

- 14747E **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)
- 14748F **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)
- 14749G **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)
- 14750H **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Abrilada*)
- 14751J **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Abrilada*)
- 14764C **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Abrilada*)
- 14772L **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)
- 14777R **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Abrilada*)
- 14782B **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINE**, amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine tablet: modified release, 6 x 100 g (*PKU Easy Microtabs Plus*)
- 14781Y **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**, amino acid formula with vitamins and minerals without lysine and low in tryptophan containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets (*GA explore5*)
- 14775P **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**, amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets (*MMA/PA explore5*)
- 14755N **DABRAFENIB**, dabrafenib 50 mg capsule, 120 (*Tafinlar*)
- 14760W **DABRAFENIB**, dabrafenib 50 mg capsule, 120 (*Tafinlar*)
- 14778T **DABRAFENIB**, dabrafenib 50 mg capsule, 120 (*Tafinlar*)
- 14754M **DABRAFENIB**, dabrafenib 75 mg capsule, 120 (*Tafinlar*)
- 14757Q **DABRAFENIB**, dabrafenib 75 mg capsule, 120 (*Tafinlar*)
- 14766E **DABRAFENIB**, dabrafenib 75 mg capsule, 120 (*Tafinlar*)
- 14752K **DABRAFENIB**, dabrafenib 10 mg dispersible tablet, 2 x 210 (*Tafinlar*)
- 14753L **DABRAFENIB**, dabrafenib 10 mg dispersible tablet, 2 x 210 (*Tafinlar*)
- 14773M **DABRAFENIB**, dabrafenib 10 mg dispersible tablet, 2 x 210 (*Tafinlar*)
- 14743Y **MOMELOTINIB**, momelotinib 100 mg tablet, 30 (*Omijara*)

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14769H	<b>MOMELOTINIB</b> , momelotinib 100 mg tablet, 30 ( <i>Omjara</i> )
14744B	<b>MOMELOTINIB</b> , momelotinib 150 mg tablet, 30 ( <i>Omjara</i> )
14762Y	<b>MOMELOTINIB</b> , momelotinib 150 mg tablet, 30 ( <i>Omjara</i> )
14763B	<b>MOMELOTINIB</b> , momelotinib 200 mg tablet, 30 ( <i>Omjara</i> )
14770J	<b>MOMELOTINIB</b> , momelotinib 200 mg tablet, 30 ( <i>Omjara</i> )
14768G	<b>PROPYLENE GLYCOL</b> , propylene glycol 0.6% eye drops, 10 mL ( <i>Systane Balance</i> )
14742X	<b>TRAMETINIB</b> , trametinib 50 microgram/mL powder for oral liquid, 90 mL ( <i>Mekinist</i> )
14761X	<b>TRAMETINIB</b> , trametinib 50 microgram/mL powder for oral liquid, 90 mL ( <i>Mekinist</i> )
14779W	<b>TRAMETINIB</b> , trametinib 500 microgram tablet, 30 ( <i>Mekinist</i> )
14780X	<b>TRAMETINIB</b> , trametinib 500 microgram tablet, 30 ( <i>Mekinist</i> )
14767F	<b>TRAMETINIB</b> , trametinib 2 mg tablet, 30 ( <i>Mekinist</i> )
14774N	<b>TRAMETINIB</b> , trametinib 2 mg tablet, 30 ( <i>Mekinist</i> )

**Addition – Brand**

12338J	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12359L	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12361N	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12364R	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12378L	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12379M	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12380N	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12382Q	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12391E	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12397L	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12398M	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12399N	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12400P	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12405X	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12410E	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12413H	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12421R	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12422T	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12430F	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12442W	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12451H	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12453K	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12455M	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13208E	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13209F	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13213K	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13216N	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13217P	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13218Q	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13219R	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13220T	<i>Hyrimoz</i> , SZ – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

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13222X	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13704G	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13732R	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13763J	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
14586Q	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
14591Y	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
14628X	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
14629Y	<i>Hyrimoz, SZ – ADALIMUMAB</i> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
10022L	<i>ERLOTINIB ARX, XT – ERLOTINIB</i> , erlotinib 25 mg tablet, 30
10028T	<i>ERLOTINIB ARX, XT – ERLOTINIB</i> , erlotinib 25 mg tablet, 30
11263T	<i>ERLOTINIB ARX, XT – ERLOTINIB</i> , erlotinib 25 mg tablet, 30
5262Y	<i>Fingolimod Dr.Reddy's, RZ – FINGOLIMOD</i> , fingolimod 500 microgram capsule, 28
10839L	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10840M	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10843Q	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10844R	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10848Y	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
8128T	<i>Metvant (Fatty), NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10834F	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10836H	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10845T	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10846W	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
10853F	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
8055Y	<i>Metvant, NB – METHYLPREDNISOLONE</i> , methylprednisolone aceponate 0.1% ointment, 15 g
11683X	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
12272X	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
14364B	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
14533X	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
14558F	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
14708D	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
8331L	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
8333N	<i>OMEPRazole-WGR, WG – OMEPRazole</i> , omeprazole 20 mg enteric tablet, 30
11410M	<i>ARX-Pirfenidone, XW – PIRFENIDONE</i> , pirfenidone 801 mg tablet, 90
12192Q	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 2.5 mg tablet, 60
12197Y	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 2.5 mg tablet, 60
13366L	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 2.5 mg tablet, 60
11633G	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 10 mg tablet, 30
13521P	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 10 mg tablet, 30
9467G	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 10 mg tablet, 30
13463N	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 15 mg tablet, 28
2160Q	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 15 mg tablet, 42
2691P	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 15 mg tablet, 28
13462M	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 20 mg tablet, 28
2268J	<i>Rivaroxaban Lupin, GQ – RIVAROXABAN</i> , rivaroxaban 20 mg tablet, 28

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11123K	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
11123K	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
13570F	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
13570F	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
11131W	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
11131W	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
13511D	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
13511D	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
11122J	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
11122J	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
13445P	<i>Pharmacor Sacubitril/Valsartan, CR – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
13445P	<i>Valtresto, RM – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
11600M	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 15 mg tablet [28] (&amp;) tolvaptan 45 mg tablet [28], 56</i>
11602P	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 15 mg tablet [28] (&amp;) tolvaptan 45 mg tablet [28], 56</i>
11588X	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 90 mg tablet [28], 56</i>
11593E	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 60 mg tablet [28], 56</i>
11596H	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 90 mg tablet [28], 56</i>
11597J	<i>Tolvaptan Lupin, GQ – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 60 mg tablet [28], 56</i>

**Addition – Equivalence Indicator**

14244Q	<i>Humira, VE – <b>ADALIMUMAB</b>, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes</i>
14245R	<i>Humira, VE – <b>ADALIMUMAB</b>, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes</i>
14275H	<i>Humira, VE – <b>ADALIMUMAB</b>, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes</i>
11123K	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
13570F	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56</i>
11131W	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
13511D	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56</i>
11122J	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
13445P	<i>Entresto, NV – <b>SACUBITRIL + VALSARTAN</b>, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56</i>
11600M	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 15 mg tablet [28] (&amp;) tolvaptan 45 mg tablet [28], 56</i>
11602P	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 15 mg tablet [28] (&amp;) tolvaptan 45 mg tablet [28], 56</i>
11588X	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 90 mg tablet [28], 56</i>
11593E	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 60 mg tablet [28], 56</i>
11596H	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 90 mg tablet [28], 56</i>
11597J	<i>Jinarc, OS – <b>TOLVAPTAN</b>, tolvaptan 30 mg tablet [28] (&amp;) tolvaptan 60 mg tablet [28], 56</i>

**Addition – Note**

14244Q	<b>ADALIMUMAB</b> , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes ( <i>Humira</i> )
14245R	<b>ADALIMUMAB</b> , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes ( <i>Humira</i> )
14275H	<b>ADALIMUMAB</b> , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes ( <i>Humira</i> )

**Addition – Restriction**

10206E	<b>EMPAGLIFLOZIN</b> , empagliflozin 10 mg tablet, 30 ( <i>Jardiance</i> )
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13845Q	<b>EMPAGLIFLOZIN</b> , empagliflozin 10 mg tablet, 30 ( <i>Jardiance</i> )
10202Y	<b>EMPAGLIFLOZIN</b> , empagliflozin 25 mg tablet, 30 ( <i>Jardiance</i> )
13920P	<b>EMPAGLIFLOZIN</b> , empagliflozin 25 mg tablet, 30 ( <i>Jardiance</i> )
10627H	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 5 mg/1000 mg</i> )
13852C	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 5 mg/1000 mg</i> )
10626G	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 5 mg/500 mg</i> )
14029J	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 5 mg/500 mg</i> )
10677Y	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 12.5 mg/1000 mg</i> )
13987E	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 12.5 mg/1000 mg</i> )
10633P	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 12.5 mg/500 mg</i> )
13903R	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 12.5 mg/500 mg</i> )

## Deletions

### Deletion – Item

14522H	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules ( <i>Cellufresh</i> )
2338C	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules ( <i>Cellufresh</i> )
5506T	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules ( <i>Cellufresh</i> )
14452P	<b>CARMELLOSE SODIUM</b> , carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules ( <i>Celluvisc</i> )
2324H	<b>CARMELLOSE SODIUM</b> , carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules ( <i>Celluvisc</i> )
5505R	<b>CARMELLOSE SODIUM</b> , carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules ( <i>Celluvisc</i> )
14675J	<b>CLONAZEPAM</b> , clonazepam 2 mg tablet, 100 ( <i>Clonazepam USP (Advagen Pharma, USA)</i> )
14648Y	<b>ESTRADIOL</b> , estradiol 37.5 microgram/24 hours patch, 24 ( <i>Estramon 37.5 (Germany)</i> )
14651D	<b>ESTRADIOL</b> , estradiol 100 microgram/24 hours patch, 24 ( <i>Estramon 100 (Germany)</i> )
1502C	<b>HYDROCORTISONE ACETATE</b> , hydrocortisone acetate 10% enema, 21.1 g ( <i>Colifoam</i> )
11417X	<b>INSULIN DEGLUDEC + INSULIN ASPART</b> , insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL pen devices ( <i>Ryzodeg Flextouch</i> )
14038W	<b>MEDROXYPROGESTERONE</b> , medroxyprogesterone acetate 500 mg tablet, 30 ( <i>Provera</i> )
2728N	<b>MEDROXYPROGESTERONE</b> , medroxyprogesterone acetate 500 mg tablet, 30 ( <i>Provera</i> )
1896T	<b>PIROXICAM</b> , piroxicam 20 mg dispersible tablet, 25 ( <i>Feldene-D</i> )
5202T	<b>PIROXICAM</b> , piroxicam 20 mg dispersible tablet, 25 ( <i>Feldene-D</i> )
13821K	<b>SALBUTAMOL</b> , salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules ( <i>pms-SALBUTAMOL</i> )

### Deletion – Brand

8718W	<i>Aripic Aripiprazole, LR</i> – <b>ARIPIPRAZOLE</b> , aripiprazole 15 mg tablet, 30
8719X	<i>Aripic Aripiprazole, LR</i> – <b>ARIPIPRAZOLE</b> , aripiprazole 20 mg tablet, 30
8720Y	<i>Aripic Aripiprazole, LR</i> – <b>ARIPIPRAZOLE</b> , aripiprazole 30 mg tablet, 30
13427Q	<i>Clopidogrel Winthrop plus aspirin, WA</i> – <b>CLOPIDOGREL + ASPIRIN</b> , clopidogrel 75 mg + aspirin 100 mg tablet, 30
9296G	<i>Clopidogrel Winthrop plus aspirin, WA</i> – <b>CLOPIDOGREL + ASPIRIN</b> , clopidogrel 75 mg + aspirin 100 mg tablet, 30
14660N	<i>Estramon 50 (Germany), DZ</i> – <b>ESTRADIOL</b> , estradiol 50 microgram/24 hours patch, 24
14652E	<i>Estramon 75 (Germany), DZ</i> – <b>ESTRADIOL</b> , estradiol 75 microgram/24 hours patch, 24
8566W	<i>Recagon, OV</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

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9333F	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 50 mg tablet, 14
13867W	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 100 mg tablet, 56
9334G	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 100 mg tablet, 14
9335H	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 100 mg tablet, 56
14053P	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 150 mg tablet, 56
9336J	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 150 mg tablet, 14
9337K	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 150 mg tablet, 56
13951G	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 200 mg tablet, 56
9338L	<i>Lacoress, LR</i> – <b>LACOSAMIDE</b> , lacosamide 200 mg tablet, 56
14000W	<i>Mycophenolate APOTEX, GX</i> – <b>MYCOPHENOLATE</b> , mycophenolate mofetil 500 mg tablet, 50
8650G	<i>Mycophenolate APOTEX, GX</i> – <b>MYCOPHENOLATE</b> , mycophenolate mofetil 500 mg tablet, 50
8186W	<i>Olanzapine APOTEX, GX</i> – <b>OLANZAPINE</b> , olanzapine 7.5 mg tablet, 28
5295Q	<i>Aloxi, JZ</i> – <b>PALONOSETRON</b> , palonosetron 250 microgram/5 mL injection, 5 mL vial
8456C	<i>Quetiapine APOTEX, GX</i> – <b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60
8458E	<i>Quetiapine APOTEX, GX</i> – <b>QUETIAPINE</b> , quetiapine 200 mg tablet, 60
8580N	<i>Quetiapine APOTEX, GX</i> – <b>QUETIAPINE</b> , quetiapine 300 mg tablet, 60
11276L	<i>Tenofovir/Emtricitabine 300/200 APOTEX, TX</i> – <b>TENOFOVIR DISOPROXIL + EMTRICITABINE</b> , tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

**Deletion – Equivalence Indicator**

1806C	<i>Paxam 2, AF</i> – <b>CLONAZEPAM</b> , clonazepam 2 mg tablet, 100
14660N	<i>Estramon (Germany, Sandoz), SZ</i> – <b>ESTRADIOL</b> , estradiol 50 microgram/24 hours patch, 24
14652E	<i>Estramon (Germany, Sandoz), SZ</i> – <b>ESTRADIOL</b> , estradiol 75 microgram/24 hours patch, 24
14715L	<i>Estramon (Germany, Sandoz), SZ</i> – <b>ESTRADIOL</b> , estradiol 100 microgram/24 hours patch, 24
8566W	<i>Puregon 600 IU/0.72 mL, OQ</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

**Deletion – Note**

1806C	<b>CLONAZEPAM</b> , clonazepam 2 mg tablet, 100 ( <i>Paxam 2</i> )
14715L	<b>ESTRADIOL</b> , estradiol 100 microgram/24 hours patch, 24 ( <i>Estramon (Germany, Sandoz)</i> )
10616R	<b>RUXOLITINIB</b> , ruxolitinib 5 mg tablet, 56 ( <i>Jakavi</i> )
10927D	<b>RUXOLITINIB</b> , ruxolitinib 10 mg tablet, 56 ( <i>Jakavi</i> )
10615Q	<b>RUXOLITINIB</b> , ruxolitinib 15 mg tablet, 56 ( <i>Jakavi</i> )
10617T	<b>RUXOLITINIB</b> , ruxolitinib 20 mg tablet, 56 ( <i>Jakavi</i> )
11123K	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
13570F	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
11131W	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
13511D	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
11122J	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
13445P	<b>SACUBITRIL + VALSARTAN</b> , sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56 ( <i>Entresto, Pharmacor Sacubitril/Valsartan, Valtresto</i> )
11600M	<b>TOLVAPTAN</b> , tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )
11602P	<b>TOLVAPTAN</b> , tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )
11588X	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )

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11593E	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )
11596H	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )
11597J	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56 ( <i>Jinarc, Tolvaptan Lupin</i> )
12457P	<b>TOLVAPTAN</b> , tolvaptan 15 mg tablet, 28 ( <i>Jinarc</i> )
12460T	<b>TOLVAPTAN</b> , tolvaptan 15 mg tablet, 28 ( <i>Jinarc</i> )
12461W	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet, 28 ( <i>Jinarc</i> )
12462X	<b>TOLVAPTAN</b> , tolvaptan 30 mg tablet, 28 ( <i>Jinarc</i> )

## Alterations

### Alteration – Note

11852T	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 10 mL ( <i>Evolve Carmellose</i> )
11853W	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 10 mL ( <i>Evolve Carmellose</i> )
14319P	<b>CARMELLOSE SODIUM</b> , carmellose sodium 0.5% eye drops, 10 mL ( <i>Evolve Carmellose</i> )
10206E	<b>EMPAGLIFLOZIN</b> , empagliflozin 10 mg tablet, 30 ( <i>Jardiance</i> )
13845Q	<b>EMPAGLIFLOZIN</b> , empagliflozin 10 mg tablet, 30 ( <i>Jardiance</i> )
10202Y	<b>EMPAGLIFLOZIN</b> , empagliflozin 25 mg tablet, 30 ( <i>Jardiance</i> )
13920P	<b>EMPAGLIFLOZIN</b> , empagliflozin 25 mg tablet, 30 ( <i>Jardiance</i> )
10627H	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 5 mg/1000 mg</i> )
13852C	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 5 mg/1000 mg</i> )
10626G	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 5 mg/500 mg</i> )
14029J	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 5 mg/500 mg</i> )
10677Y	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 12.5 mg/1000 mg</i> )
13987E	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Jardiamet 12.5 mg/1000 mg</i> )
10633P	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 12.5 mg/500 mg</i> )
13903R	<b>EMPAGLIFLOZIN + METFORMIN</b> , empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Jardiamet 12.5 mg/500 mg</i> )
14354L	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.1% eye drops, 10 mL ( <i>Hylo-Fresh</i> )
2181T	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.1% eye drops, 10 mL ( <i>Hylo-Fresh</i> )
2184Y	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.1% eye drops, 10 mL ( <i>Hylo-Fresh</i> )
14494W	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.2% eye drops, 10 mL ( <i>Hylo-Forte</i> )
2171G	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.2% eye drops, 10 mL ( <i>Hylo-Forte</i> )
2253N	<b>HYALURONATE SODIUM</b> , hyaluronate sodium 0.2% eye drops, 10 mL ( <i>Hylo-Forte</i> )
11842G	<b>HYPROMELLOSE</b> , hypromellose 0.3% w/v eye drops, 10 mL ( <i>Evolve Hypromellose</i> )
11849P	<b>HYPROMELLOSE</b> , hypromellose 0.3% w/v eye drops, 10 mL ( <i>Evolve Hypromellose</i> )
14492R	<b>HYPROMELLOSE</b> , hypromellose 0.3% w/v eye drops, 10 mL ( <i>Evolve Hypromellose</i> )
12612T	<b>LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE</b> , liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL ( <i>Cationorm</i> )
14352J	<b>LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE</b> , liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL ( <i>Cationorm</i> )
10614P	<b>RUXOLITINIB</b> , ruxolitinib 5 mg tablet, 56 ( <i>Jakavi</i> )
10913J	<b>RUXOLITINIB</b> , ruxolitinib 10 mg tablet, 56 ( <i>Jakavi</i> )



10619X **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)  
 10618W **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)

**Alteration – Restriction**

14625R **BIMEKIZUMAB**, bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices (*Bimzelx*)  
 11365E **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (*Simponi*)  
 3430M **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (*Simponi*)  
 2181T **HYALURONATE SODIUM**, hyaluronate sodium 0.1% eye drops, 10 mL (*Hylo-Fresh*)  
 2184Y **HYALURONATE SODIUM**, hyaluronate sodium 0.1% eye drops, 10 mL (*Hylo-Fresh*)  
 2171G **HYALURONATE SODIUM**, hyaluronate sodium 0.2% eye drops, 10 mL (*Hylo-Forte*)  
 2253N **HYALURONATE SODIUM**, hyaluronate sodium 0.2% eye drops, 10 mL (*Hylo-Forte*)  
 14732J **RISANKIZUMAB**, risankizumab 150 mg/mL injection, 1 mL pen device (*Skyrizi*)  
 10614P **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)  
 10616R **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)  
 10913J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)  
 10927D **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)  
 10615Q **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)  
 10619X **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)  
 10617T **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)  
 10618W **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)  
 10894J **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (*Cosentyx*)  
 10900Q **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL pen device (*Cosentyx*)  
 11690G **TOFACITINIB**, tofacitinib 5 mg tablet, 56 (*Xeljanz*)  
 12624K **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)

**Alteration – Restriction Level**

10616R	<b>RUXOLITINIB</b> , ruxolitinib 5 mg tablet, 56 ( <i>Jakavi</i> )	From authority- required	To streamlined
10927D	<b>RUXOLITINIB</b> , ruxolitinib 10 mg tablet, 56 ( <i>Jakavi</i> )	authority- required	streamlined
10615Q	<b>RUXOLITINIB</b> , ruxolitinib 15 mg tablet, 56 ( <i>Jakavi</i> )	authority- required	streamlined
10617T	<b>RUXOLITINIB</b> , ruxolitinib 20 mg tablet, 56 ( <i>Jakavi</i> )	authority- required	streamlined

**Alteration – Manufacturer Code**

11621P	<i>Roaccutane</i> – <b>ISOTRETINOIN</b> , isotretinoin 20 mg capsule, 30	From RO	To PB
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**Supply Only**

**Supply Only – Period Commencing**

14478B **GLYCERYL TRINITRATE**, glyceryl trinitrate 10 mg/24 hours patch, 30 (*Minitran 10*)  
 8028M **GLYCERYL TRINITRATE**, glyceryl trinitrate 10 mg/24 hours patch, 30 (*Minitran 10*)  
 1590Q **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28 (*Orudis SR 200*)  
 5136H **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28 (*Orudis SR 200*)  
 1747Y **PARACETAMOL**, paracetamol 24 mg/mL oral liquid, 100 mL (*Panamax*)  
 3348F **PARACETAMOL**, paracetamol 24 mg/mL oral liquid, 100 mL (*Panamax*)  
 13563W **RAMIPRIL + FELODIPINE**, ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30 (*Triasyn 2.5/2.5*)  
 2626F **RAMIPRIL + FELODIPINE**, ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30 (*Triasyn 2.5/2.5*)

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**Supply Only – Period Ending**

12704P	<b>DARATUMUMAB</b> , daratumumab 1.8 g/15 mL injection, 15 mL vial ( <i>Darzalex SC</i> )
12645M	<b>OBETICHOLIC ACID</b> , obeticholic acid 5 mg tablet, 30 ( <i>Ocaliva</i> )
12631T	<b>OBETICHOLIC ACID</b> , obeticholic acid 10 mg tablet, 30 ( <i>Ocaliva</i> )

**Advance Notices****1 May 2025****Deletion – Brand**

8362D	<i>Capecitabine Alphapharm, AF</i> – <b>CAPECITABINE</b> , capecitabine 500 mg tablet, 120
1758M	<i>DBL Cefotaxime, PF</i> – <b>CEFOTAXIME</b> , cefotaxime 1 g injection, 10 vials
1768C	<i>DBL Cefotaxime, PF</i> – <b>CEFOTAXIME</b> , cefotaxime 1 g injection, 10 vials
1288T	<i>Maxidex, NV</i> – <b>DEXAMETHASONE</b> , dexamethasone 0.1% eye drops, 5 mL
5565X	<i>Maxidex, NV</i> – <b>DEXAMETHASONE</b> , dexamethasone 0.1% eye drops, 5 mL
8565T	<i>Recagon, OV</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge
8871X	<i>Recagon, OV</i> – <b>FOLLITROPIN BETA</b> , follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge
2824P	<i>Pfizer Australia Pty Ltd, PF</i> – <b>GENTAMICIN</b> , gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules
13412X	<i>Lercanidipine APOTEX, GX</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 20 mg tablet, 28
8679T	<i>Lercanidipine APOTEX, GX</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 20 mg tablet, 28
11739W	<i>Solu-Medrol, PF</i> – <b>METHYLPREDNISOLONE</b> , methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial
5264C	<i>Methylpred, AL</i> – <b>METHYLPREDNISOLONE</b> , methylprednisolone 1 g injection, 1 vial
14203M	<i>RA-Morph (NZ), WZ</i> – <b>MORPHINE</b> , morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL
14220K	<i>RA-Morph (NZ), WZ</i> – <b>MORPHINE</b> , morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL
13371R	<i>Indosyl Mono 4, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 4 mg tablet, 30
13372T	<i>Indosyl Mono 8, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 8 mg tablet, 30
13404L	<i>Indosyl Mono 2, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 2 mg tablet, 30
3050M	<i>Indosyl Mono 2, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 2 mg tablet, 30
3051N	<i>Indosyl Mono 4, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 4 mg tablet, 30
8704D	<i>Indosyl Mono 8, RW</i> – <b>PERINDOPRIL</b> , perindopril erbumine 8 mg tablet, 30
13476G	<i>Indosyl Combi 4/1.25, RW</i> – <b>PERINDOPRIL + INDAPAMIDE</b> , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
8449Q	<i>Indosyl Combi 4/1.25, RW</i> – <b>PERINDOPRIL + INDAPAMIDE</b> , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
14421B	<i>Optix, PP</i> – <b>POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL</b> , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL
5524R	<i>Optix, PP</i> – <b>POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL</b> , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL
8676P	<i>Optix, PP</i> – <b>POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL</b> , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL
9447F	<i>Biltricide, BN</i> – <b>PRAZQUANTEL</b> , praziquantel 600 mg tablet, 8
12160B	<i>Mayzent, NV</i> – <b>SIPONIMOD</b> , siponimod 250 microgram tablet, 120
13128Y	<i>TNKase (Canada), QY</i> – <b>TENECTEPLASE</b> , tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack
13128Y	<i>TNKase (Canada) Medsurge Healthcare Pty Ltd, DZ</i> – <b>TENECTEPLASE</b> , tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack
2328M	<i>Tobrex, NV</i> – <b>TOBRAMYCIN</b> , tobramycin 0.3% eye drops, 5 mL
2329N	<i>Tobrex, NV</i> – <b>TOBRAMYCIN</b> , tobramycin 0.3% eye ointment, 3.5 g
5569D	<i>Tobrex, NV</i> – <b>TOBRAMYCIN</b> , tobramycin 0.3% eye drops, 5 mL
5570E	<i>Tobrex, NV</i> – <b>TOBRAMYCIN</b> , tobramycin 0.3% eye ointment, 3.5 g

### ***Deletion – Brand***

[illegible]

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14338P	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 200 mg tablet, 100
14509P	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 100 mg tablet, 100
1706T	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 200 mg tablet, 100
1724R	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 200 mg tablet, 100
2422L	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 100 mg tablet, 100
5039F	<i>Carbamazepine Sandoz, NM</i> – <b>CARBAMAZEPINE</b> , carbamazepine 100 mg tablet, 100
13883Q	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 25 mg capsule, 30
13910D	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 50 mg capsule, 30
13911E	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 100 mg capsule, 30
8658Q	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 25 mg capsule, 30
8659R	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 50 mg capsule, 30
8660T	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 100 mg capsule, 30
5096F	<i>Dicloxacillin Mylan 250, AL</i> – <b>DICLOXACILLIN</b> , dicloxacillin 250 mg capsule, 24
8121K	<i>Dicloxacillin Mylan 250, AL</i> – <b>DICLOXACILLIN</b> , dicloxacillin 250 mg capsule, 24
8187X	<i>Olanzapine APOTEX, GX</i> – <b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28
1594X	<i>Ondansetron Mylan Tablets, AF</i> – <b>ONDANSETRON</b> , ondansetron 4 mg tablet, 10
1595Y	<i>Ondansetron Mylan Tablets, AF</i> – <b>ONDANSETRON</b> , ondansetron 8 mg tablet, 10
5471Y	<i>Ondansetron Mylan ODT, AF</i> – <b>ONDANSETRON</b> , ondansetron 8 mg orally disintegrating tablet, 4
5473C	<i>Ondansetron Mylan ODT, AF</i> – <b>ONDANSETRON</b> , ondansetron 8 mg orally disintegrating tablet, 10
8224W	<i>Ondansetron Mylan Tablets, AF</i> – <b>ONDANSETRON</b> , ondansetron 4 mg tablet, 4
8225X	<i>Ondansetron Mylan Tablets, AF</i> – <b>ONDANSETRON</b> , ondansetron 8 mg tablet, 4
13586C	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
2628H	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30

### 1 July 2025

#### Deletion – Brand

1007B	<i>Aciclovir APOTEX, TY</i> – <b>ACICLOVIR</b> , aciclovir 200 mg tablet, 90
13358C	<i>Allopurinol APOTEX, GX</i> – <b>ALLOPURINOL</b> , allopurinol 100 mg tablet, 200
2600W	<i>Allopurinol APOTEX, GX</i> – <b>ALLOPURINOL</b> , allopurinol 100 mg tablet, 200
13532F	<i>Amlodipine APOTEX, GX</i> – <b>AMLODIPINE</b> , amlodipine 5 mg tablet, 30
2751T	<i>Amlodipine APOTEX, GX</i> – <b>AMLODIPINE</b> , amlodipine 5 mg tablet, 30
8844L	<i>Bivalirudin APOTEX, TX</i> – <b>BIVALIRUDIN</b> , bivalirudin 250 mg injection, 1 vial
14740T	<i>Glyade MR, AF</i> – <b>GLICLAZIDE</b> , gliclazide 30 mg modified release tablet, 100
8535F	<i>Glyade MR, AF</i> – <b>GLICLAZIDE</b> , gliclazide 30 mg modified release tablet, 100
13848W	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 1 mg tablet, 30
13870B	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 2 mg tablet, 30
14020X	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 3 mg tablet, 30
14055R	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 4 mg tablet, 30
8450R	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 1 mg tablet, 30
8451T	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 2 mg tablet, 30
8452W	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 4 mg tablet, 30
8533D	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 3 mg tablet, 30
14335L	<i>Minitran 15, IL</i> – <b>GLYCERYL TRINITRATE</b> , glyceryl trinitrate 15 mg/24 hours patch, 30
8119H	<i>Minitran 15, IL</i> – <b>GLYCERYL TRINITRATE</b> , glyceryl trinitrate 15 mg/24 hours patch, 30
13940Q	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30

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13998R	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
14068K	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30
14069L	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
5449T	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30
5450W	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
8374R	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 10 mg tablet, 30
8375T	<i>Leflunomide APOTEX, GX</i> – <b>LEFLUNOMIDE</b> , leflunomide 20 mg tablet, 30
13411W	<i>Lercanidipine APOTEX, GX</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 10 mg tablet, 28
8534E	<i>Lercanidipine APOTEX, GX</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 10 mg tablet, 28
13939P	<i>Letrozole APOTEX, GX</i> – <b>LETROZOLE</b> , letrozole 2.5 mg tablet, 30
8245Y	<i>Letrozole APOTEX, GX</i> – <b>LETROZOLE</b> , letrozole 2.5 mg tablet, 30
13937M	<i>Levetiracetam Mylan, AL</i> – <b>LEVETIRACETAM</b> , levetiracetam 1 g tablet, 60
13992K	<i>Levetiracetam Mylan, AL</i> – <b>LEVETIRACETAM</b> , levetiracetam 250 mg tablet, 60
8654L	<i>Levetiracetam Mylan, AL</i> – <b>LEVETIRACETAM</b> , levetiracetam 250 mg tablet, 60
8656N	<i>Levetiracetam Mylan, AL</i> – <b>LEVETIRACETAM</b> , levetiracetam 1 g tablet, 60
10526B	<i>Latuda, SE</i> – <b>LURASIDONE</b> , lurasidone hydrochloride 40 mg tablet, 30
10529E	<i>Latuda, SE</i> – <b>LURASIDONE</b> , lurasidone hydrochloride 80 mg tablet, 30
8170B	<i>Olanzapine APOTEX, GX</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
11681T	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
12277E	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
14330F	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
14362X	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
14394N	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
8007K	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
8008L	<i>Pantoprazole APOTEX, TY</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg enteric tablet, 30
13588E	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
13589F	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
2574L	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
2594M	<i>Rosuvastatin APOTEX, GX</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
11856B	<i>Sevelamer Apotex, TX</i> – <b>SEVELAMER</b> , sevelamer carbonate 800 mg tablet, 180
14027G	<i>Sevelamer Apotex, TX</i> – <b>SEVELAMER</b> , sevelamer carbonate 800 mg tablet, 180

## Palliative Care

### Deletions

#### **Deletion – Item**

14674H **CLONAZEPAM**, clonazepam 2 mg tablet, 100 (*Clonazepam USP (Advagen Pharma, USA)*)

#### **Deletion – Equivalence Indicator**

5338Y *Paxam 2, AF* – **CLONAZEPAM**, clonazepam 2 mg tablet, 100

#### **Deletion – Note**

5338Y **CLONAZEPAM**, clonazepam 2 mg tablet, 100 (*Paxam 2*)

## Advance Notices

### **1 May 2025**

#### **Deletion – Brand**

14186P *RA-Morph (NZ), WZ* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

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## Highly Specialised Drugs Program (Private Hospital)

### Additions

#### Addition – Item

- 14746D **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial (*Ultomiris*)
- 14771K **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial (*Ultomiris*)
- 14745C **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial (*Ultomiris*)
- 14776Q **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial (*Ultomiris*)

#### Addition – Brand

- 12396K *Hyrimoz, SZ* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
- 13210G *Hyrimoz, SZ* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

### Deletions

#### Deletion – Brand

- 11036W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 11966T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28
- 12038N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 12058P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14
- 12071H *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 12984J *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 13642B *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 2798G *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 9642L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21
- 11063G *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 11969Y *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28
- 12004T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14
- 12050F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 12060R *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 12980E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 13658W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 2796E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 9643M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21
- 11042E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 11965R *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28
- 12011E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 12020P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 12069F *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14
- 12986L *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 13657T *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 9644N *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21
- 11055W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21
- 12018M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14
- 12037M *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21
- 12068E *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21
- 12993W *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21
- 13660Y *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21
- 9645P *Lenalidomide-Teva, TB* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

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6209T      *Mycophenolate APOTEX, GX – MYCOPHENOLATE*, mycophenolate mofetil 500 mg tablet, 50

## Alterations

### Alteration – Note

11036W	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11966T	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 28 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12038N	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12058P	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12071H	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12984J	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13642B	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
2798G	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
9642L	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11063G	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11969Y	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 28 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12004T	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12050F	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12060R	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12980E	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13658W	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
2796E	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
9643M	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11042E	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11965R	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 28 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12011E	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12020P	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12069F	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12986L	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13657T	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )

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9644N	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
14582L	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14583M	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14609X	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14610Y	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14615F	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 14 ( <i>Lenalide</i> )
14624Q	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14631C	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
11055W	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12018M	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12037M	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12068E	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12993W	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13660Y	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
9645P	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )

## Advance Notices

**1 June 2025**

### Deletion – Brand

12335F	<i>Adalicip, LR</i> – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
13229G	<i>Adalicip, LR</i> – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
12784W	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13033Y	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13038F	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13039G	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13040H	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
6100C	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
6138C	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
6352H	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 25 mg capsule, 30
6353J	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 50 mg capsule, 30
6354K	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 100 mg capsule, 30

**1 July 2025**

### Deletion – Brand

11838C	<i>Sevelamer Apotex, TX</i> – <b>SEVELAMER</b> , sevelamer carbonate 800 mg tablet, 180
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## Highly Specialised Drugs Program (Public Hospital)

### Additions

#### Addition – Item

14759T	<b>RAVULIZUMAB</b> , ravulizumab 300 mg/3 mL injection, 3 mL vial ( <i>Ultomiris</i> )
14784D	<b>RAVULIZUMAB</b> , ravulizumab 300 mg/3 mL injection, 3 mL vial ( <i>Ultomiris</i> )
14758R	<b>RAVULIZUMAB</b> , ravulizumab 1.1 g/11 mL injection, 11 mL vial ( <i>Ultomiris</i> )



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14783C     **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial (*Ultomiris*)

**Addition – Brand**

12431G     *Hyrimoz*, SZ – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13228F     *Hyrimoz*, SZ – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

**Deletions**

**Deletion – Brand**

11029L     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11967W     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12034J     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12035K     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12039P     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12985K     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

13636Q     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2799H     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

5783J     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11064H     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11968X     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12057N     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12061T     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12070G     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12988N     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

13661B     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2802L     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

5784K     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11062F     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11964Q     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12012F     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12026Y     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12062W     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12991R     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

13641Y     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

5785L     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11041D     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12019N     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12036L     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

13630J     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M     *Lenalidomide-Teva*, TB – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9502D     *Mycophenolate APOTEX*, GX – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

**Alterations**

**Alteration – Note**

11029L     **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Lenalide*, *Lenalidomide Dr.Reddy's*, *Lenalidomide Sandoz*, *Lenalidomide Viatris*, , *Revlimid*)

11967W     **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 (*Lenalide*, *Lenalidomide Dr.Reddy's*, *Lenalidomide Sandoz*, , *Revlimid*)

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12034J	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12035K	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12039P	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12985K	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13636Q	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
2799H	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
5783J	<b>LENALIDOMIDE</b> , lenalidomide 5 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11064H	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11968X	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 28 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12057N	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12061T	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12070G	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12988N	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13661B	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
2802L	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
5784K	<b>LENALIDOMIDE</b> , lenalidomide 10 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11062F	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
11964Q	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 28 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12012F	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12026Y	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12062W	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12991R	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13641Y	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
5785L	<b>LENALIDOMIDE</b> , lenalidomide 15 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
14588T	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14592B	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14608W	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14616G	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14623P	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 14 ( <i>Lenalide</i> )

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14632D	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
14633E	<b>LENALIDOMIDE</b> , lenalidomide 20 mg capsule, 21 ( <i>Lenalide, Lenalidomide Sandoz</i> )
11041D	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12019N	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 14 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, , Revlimid</i> )
12036L	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12059Q	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
12979D	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
13630J	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )
5786M	<b>LENALIDOMIDE</b> , lenalidomide 25 mg capsule, 21 ( <i>Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Lenalidomide Viatris, , Revlimid</i> )

## Advance Notices

**1 June 2025**

### Deletion – Brand

12444Y	<i>Adalicip, LR</i> – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
13212J	<i>Adalicip, LR</i> – <b>ADALIMUMAB</b> , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
12771E	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13028Q	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13036D	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13042K	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
13044M	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
9597D	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
9598E	<i>Azacitidine-Teva, TB</i> – <b>AZACITIDINE</b> , azacitidine 100 mg injection, 1 vial
5634M	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 25 mg capsule, 30
5635N	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 50 mg capsule, 30
5636P	<i>Cyclosporin Sandoz, NM</i> – <b>CICLOSPORIN</b> , ciclosporin 100 mg capsule, 30

**1 July 2025**

### Deletion – Brand

11855Y	<i>Sevelamer Apotex, TX</i> – <b>SEVELAMER</b> , sevelamer carbonate 800 mg tablet, 180
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## Highly Specialised Drugs Program (Community Access)

### Deletions

#### Deletion – Brand

10347N	<i>Tenofovir/Emtricitabine 300/200 APOTEX, TX</i> – <b>TENOFOVIR DISOPROXIL + EMTRICITABINE</b> , tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30
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### Supply Only

#### Supply Only – Period Commencing

10290N	<b>ADEFOVIR</b> , adefovir dipivoxil 10 mg tablet, 30 ( <i>APO-Adefovir</i> )
10303G	<b>NEVIRAPINE</b> , nevirapine 400 mg modified release tablet, 30 ( <i>Viramune XR</i> )

## Advance Notices

**1 May 2025**

### Deletion – Brand

13777D	<i>Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories), XW</i> – <b>ADEFOVIR</b> , adefovir dipivoxil 10 mg tablet, 30
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## IVF Program

### Deletions

#### **Deletion – Brand**

6336L      *Recagon*, OV – **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

#### **Deletion – Equivalence Indicator**

6336L      *Puregon 600 IU/0.72 mL*, OQ – **FOLLITROPIN BETA**, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

### Alterations

#### **Alteration – Restriction**

11667C      **FOLLITROPIN ALFA + LUTROPIN ALFA**, follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device (*Pergoveris*)

#### **Alteration – Maximum Quantity**

		<i>From</i>	<i>To</i>
11667C	<b>FOLLITROPIN ALFA + LUTROPIN ALFA</b> , follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device ( <i>Pergoveris</i> )	2	4

### Advance Notices

#### **1 May 2025**

#### **Deletion – Brand**

6335K      *Recagon*, OV – **FOLLITROPIN BETA**, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

6464F      *Recagon*, OV – **FOLLITROPIN BETA**, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge



# About the Schedule

The Schedule of Pharmaceutical Benefits lists all of the ready-prepared items subsidised under the Pharmaceutical Benefits Scheme (PBS).

The Schedule is published and is effective on the first day of each month.

For detailed information about the prescribing and supply of pharmaceutical benefits go to [www.pbs.gov.au](http://www.pbs.gov.au)

For information about the operational aspects of the PBS, such as, PBS claiming, authority applications and stationery supplies contact Services Australia at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

The Repatriation Schedule of Pharmaceutical Benefits provides information about pharmaceutical benefits available under the Repatriation Pharmaceutical Benefits Scheme (RPBS). These may only be prescribed to Department of Veterans' Affairs (DVA) beneficiaries holding a valid repatriation health card. Queries relating to the RPBS can be made to the DVA or go to [www.dva.gov.au](http://www.dva.gov.au)

## Symbols and Abbreviations Used in the Schedule

*	An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity
‡	A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed
#	A gauge in the dispensed price column indicates that the product is not preconstituted and that the dispensed price therefore included a dispensing fee and where appropriate, an amount for purified water
a or b	Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect
B	Located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item
T	Located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item
S	Located immediately before an amount in the premium column indicates a special patient contribution which applies to that particular item
DPMQ \$	Dispensed price for maximum quantity
MRVSN \$	Maximum recordable value for safety net
NP	Indicates that the item can be prescribed by an authorised nurse practitioner
MW	Indicates that the item can be prescribed by an authorised midwife
OP	Indicates that the item can be prescribed by an authorised optometrist
DP	Indicates that the item can be prescribed by an authorised dental practitioner

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## Restricted Benefits

All restricted items have separate headings for authority and non-authority items. In each case these items may be prescribed as pharmaceutical benefits only for use for one of the specified indications. Where more than one indication is specified for an Authority required or Restricted pharmaceutical benefit, each indication is separated from the preceding indication by a semi-colon and commences on the next line. In the case of Authority required (STREAMLINED) items, each indication will also include a four digit streamlined authority code. The drug may be prescribed as a pharmaceutical benefit for a patient who qualifies under any of the specified indications.

Restricted benefits - above an item indicates where an item can only be prescribed for specific therapeutic uses.

Authority required benefits – above an item indicates that a prescriber must seek approval from Services Australia or the Department of Veterans' Affairs. The prescriber must declare the specific conditions and circumstances that justify the use of these medicines. This is usually done by phone or in writing

Authority required (STREAMLINED) – authority can be sought electronically.

# Guidelines and General Statements

## General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

### Treatment criteria:

Must be treated by a medical practitioner or an authorised nurse practitioner experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

The following information must be provided at the time of application:

- the patient's cirrhotic status (non-cirrhotic or cirrhotic)
- details of the previous treatment regimen (only for requests for sofosbuvir + velpatasvir + voxilaprevir (Vosevi®) or glecaprevir + pibrentasvir (Maviret®) for 16 weeks' treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

The following information must be documented in the patient's medical records:

- evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
- where possible, evidence of the hepatitis C virus genotype

The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

### HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
<b>All genotypes</b> (Pan-genotypic regimens)	<b>SOFOSBUVIR + VELPATASVIR</b> [12 weeks] OR <b>GLECAPREVIR + PIBRENTASVIR</b> [8 weeks]	<b>SOFOSBUVIR + VELPATASVIR</b> [12 weeks] OR <b>SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR</b> [12 weeks] <sup>1</sup> OR <b>GLECAPREVIR + PIBRENTASVIR</b> [8 or 12 or 16 weeks] <sup>2</sup>

### HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
<b>All genotypes</b> (Pan-genotypic regimens)	<b>SOFOSBUVIR + VELPATASVIR</b> [12 weeks] <sup>3, 4</sup> OR <b>GLECAPREVIR + PIBRENTASVIR</b> [12 weeks] <sup>5</sup>	<b>SOFOSBUVIR + VELPATASVIR</b> [12 weeks] <sup>3, 4</sup> OR <b>SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR</b> [12 weeks] <sup>1</sup> OR <b>GLECAPREVIR + PIBRENTASVIR</b> [12 or 16 weeks] <sup>6</sup>

<sup>1</sup>. SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.

<sup>2</sup>. GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:

- treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;



- 
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
3. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
  4. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.
  5. GLECAPREVIR + PIBRENTASVIR – A treatment duration of 12 weeks may be considered for patients with compensated cirrhosis, at the discretion of the prescriber.
  6. GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:
    - treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
    - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
    - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

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# Pharmaceutical Benefits Schedules

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# Prescriber Bag

## ■ ADRENALINE (EPINEPHRINE)

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

3451P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	21.10	Link Medical Products Pty Ltd [LM]

## ■ ATROPINE SULFATE

**atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

3453R	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	29.45	Atropine Injection (Bridgewest) [WZ]

## ■ BENZATHINE BENZYL PENICILLIN

**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

11755Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	335.98	<sup>a</sup> Bicillin L-A [PF]

OR

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack**

13801J	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	10	*511.97	<sup>a</sup> Extencilline Benzathine Benzylpenicillin (France) [YO]

## ■ BENZATROPINE

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

11265X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	118.61	Benzatropine Injection [FF]

## ■ BENZYL PENICILLIN

**benzylpenicillin 600 mg injection, 1 vial**

3486L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	5	*43.17	BenPen [CS]

## ■ BENZYL PENICILLIN

**benzylpenicillin 3 g injection, 1 vial**

3487M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	1	23.04	BenPen [CS]

## ■ CHLORPROMAZINE

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

3455W	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	34.45	Largactil [IX]

OR

## ■ HALOPERIDOL

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

3456X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	24.66	Serenace [AS]

## ■ CLONAZEPAM

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

3478C	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	‡1	17.22	Rivotril [PB]

## ■ DIPHTHERIA + TETANUS VACCINE

**diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes**

3463G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*178.53	ADT Booster [CS]

## FUROSEMIDE

**furosemide 20 mg/2 mL injection, 5 x 2 mL ampoules**

3466K	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	16.58	Lasix [SW]

## FUROSEMIDE

**furosemide 20 mg tablet, 50**

12222G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	16.15	<sup>a</sup> Frusemix-M [TY]	<sup>a</sup> UREMIDE 20 [AF]

## GLUCAGON HYDROCHLORIDE

**glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

3467L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	51.10	Glucagen Hypokit [NO]

## GLYCERYL TRINITRATE

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

3475X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	±1	26.09	Nitrolingual Pumpspray [SW]

## HYDROCORTISONE SODIUM SUCCINATE

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

3470P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*23.27	Solu-Cortef [PF]

OR

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

3471Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	22.22	Solu-Cortef [PF]

## HYOSCINE BUTYLBROMIDE

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

3473T	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	20.52	<sup>a</sup> Buscopan [VZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE-AFT [AE]
			<sup>a</sup> HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE SXP [XN]

## LIDOCAINE

**lidocaine hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules**

10209H	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	1	50.90	LIGNOCAINE INJECTION (BRIDGEWEST) [WZ]


## METHOXYFLURANE

**methoxyflurane 99.9% (999 mg/g) inhalation solution, 3 mL bottle**

3489P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	67.22	Pentrox (Combination Pack) [DV]

▪ **METOCLOPRAMIDE**

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

3476Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	21.09	<sup>a</sup> Metoclopramide HCl Medsurge [DZ]	<sup>a</sup> METOCLOPRAMIDE INJECTION BP [WZ]

OR

▪ **PROCHLORPERAZINE**

**prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules**

3477B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
 	1	23.78	Stemetil [IX]

▪ **MIDAZOLAM**

**midazolam 5 mg/mL injection, 10 x 1 mL ampoules**

10178Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	39.85	Pfizer Australia Pty Ltd [PF]

▪ **MOLNUPIRAVIR**

**molnupiravir 200 mg capsule, 40**

13144T	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	2	*2192.75	Lagevrio [MK]

▪ **MORPHINE**

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

10862Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	22.97	Morphine Juno [JU]


OR

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

10868B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	25.16	Morphine Juno [JU]


OR

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

3479D	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	26.55	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]



OR

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

3480E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	28.65	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

▪ **NALOXONE**

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

10786Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	2	*48.35	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF] <sup>a</sup> NALOXONE SXP [XN]	<sup>a</sup> Naloxone Juno [JU]


OR

**naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules**

11233F	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
 	1	48.34	NARCAN [FF]

▪ **NIRMATRELVIR (&) RITONAVIR**

**nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6**

13147Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	2	*2216.75	Paxlovid [PF]

## ■ PHYTOMENADIONE

### phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules

10213M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	25.63	Konakion MM [PB]

## ■ PROMETHAZINE

### promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

3488N	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	2	*36.65	DBL Promethazine Hydrochloride [PF]

NP MW

## ■ SALBUTAMOL

### salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

3497C	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	±1	18.83	Salbutamol Cipla [LR]

NP

OR

### salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11088N	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	±1	18.47	Ventolin Nebules [GK]

NP

## ■ SALBUTAMOL

### salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

3496B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	±1	18.77	Salbutamol Cipla [LR]

NP

OR

### salbutamol 100 microgram/actuation inhalation, 200 actuations

12108G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	±1	19.29	<sup>a</sup> Zempreon CFC-Free with dose counter [AL]
		19.75	<sup>a</sup> Asmol CFC-Free with dose counter [AF]
		22.29	<sup>a</sup> Ventolin CFC-Free with dose counter [GK]

NP

OR

### salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11125M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	±1	18.34	Ventolin Nebules [GK]

NP

## ■ TRAMADOL

### tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

3484J	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	17.02	<sup>a</sup> Tramadol AN [JU]	<sup>a</sup> Tramadol Sandoz [SZ]
			<sup>a</sup> Tramal 100 [CS]	

NP

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## ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antifungives and antiseptics for local oral treatment*

#### AMPHOTERICIN B

##### amphotericin B 10 mg lozenge, 20

2931G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.83	19.28	Fungilin [AS]

##### amphotericin B 10 mg lozenge, 20

3306B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	17.83	19.28	Fungilin [AS]

*Other agents for local oral treatment*

#### BENZYLAMINE

##### Restricted benefit

Mucositis

##### Clinical criteria:

- The condition must be radiation induced.

##### benzylamine hydrochloride 0.15% mouthwash, 500 mL

1121B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	22.17	23.62	Diffiam [IL]

#### BENZYLAMINE

##### Restricted benefit

Mucositis

##### Clinical criteria:

- The condition must be radiation induced.

##### benzylamine hydrochloride 0.15% mouthwash, 500 mL

5032W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	22.17	23.62	Diffiam [IL]

## DRUGS FOR ACID RELATED DISORDERS

### DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

*H2-receptor antagonists*

#### FAMOTIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

##### famotidine 20 mg tablet, 60

2487X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.45	18.90	Ausfam 20 [RW]

##### famotidine 40 mg tablet, 30

2488Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.45	18.90	Ausfam 40 [RW]

#### NIZATIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

##### nizatidine 150 mg capsule, 60

1505F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 7.59	23.90 31.49	25.35 25.35	<sup>a</sup> Nizac [RF] <sup>a</sup> Tazac [RW]	<sup>a</sup> Tacidine [AF]

##### nizatidine 300 mg capsule, 30

1504E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 7.59	23.90 31.49	25.35 25.35	<sup>a</sup> Nizac [RF] <sup>a</sup> Tazac [RW]	<sup>a</sup> Tacidine [AF]

## ■ NIZATIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### nizatidine 150 mg capsule, 60

14306Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.35	31.60	<sup>a</sup> Nizac [RF]	<sup>a</sup> Tacidine [AF]
			<sup>B</sup> 15.18	*49.53	31.60	<sup>a</sup> Tazac [RW]	

### nizatidine 300 mg capsule, 30

14372K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.35	31.60	<sup>a</sup> Nizac [RF]	<sup>a</sup> Tacidine [AF]
			<sup>B</sup> 15.18	*49.53	31.60	<sup>a</sup> Tazac [RW]	

## ■ RANITIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

### ranitidine 150 mg tablet, 60

1978D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	5	..	17.37	18.82	APO-Ranitidine [TX]

### ranitidine 300 mg tablet, 30

1977C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.37	18.82	APO-Ranitidine [TX]

### Proton pump inhibitors

## ■ ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Gastro-oesophageal reflux disease

### Clinical criteria:

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

### esomeprazole 40 mg enteric tablet, 30

8601Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.76	22.21	<sup>a</sup> APO-Esomeprazole [TY]	<sup>a</sup> Esomeprazole GH [GQ]
						<sup>a</sup> Esomeprazole GxP [AF]	<sup>a</sup> Esomeprazole RBX [RA]
						<sup>a</sup> Esomeprazole Viatris [MQ]	<sup>a</sup> ESOMEPRAZOLE-WGR [WG]
						<sup>a</sup> Esopreze [BG]	<sup>a</sup> Nexazole [RW]
						<sup>a</sup> Nexole [RF]	
						<sup>a</sup> Nexium [AP]	
			<sup>B</sup> 7.00	27.76	22.21		

### esomeprazole 40 mg enteric capsule, 30

10330Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	20.76	22.21	<sup>a</sup> Noxicid Caps [AL]

## ■ ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

### **Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

### Clinical criteria:

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

### Authority required

Scleroderma oesophagus

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**esomeprazole 40 mg enteric tablet, 30**

3401B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.76	22.21	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatrix [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 7.00	27.76	22.21	<sup>a</sup> Nexium [AP]	

**esomeprazole 40 mg enteric capsule, 30**

10331R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.76	22.21	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Authority required**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**esomeprazole 40 mg enteric tablet, 30**

14373L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*28.07	29.52	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatrix [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 14.00	*42.07	29.52	<sup>a</sup> Nexium [AP]	

**esomeprazole 40 mg enteric capsule, 30**

14405E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*28.07	29.52	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**8775**

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.



**esomeprazole 20 mg enteric tablet, 30**

8886Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.76	19.21	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 7.00	24.76	19.21	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

10295W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.76	19.21	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****8780**

Scleroderma oesophagus

**Authority required (STREAMLINED)****8827**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**esomeprazole 20 mg enteric tablet, 30**

8600P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 7.00	24.76	19.21	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

10343J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**esomeprazole 20 mg enteric tablet, 30**

11692J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 7.00	24.76	19.21	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

11687D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Noxicid Caps [AL]

■ **ESOMEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8774**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**esomeprazole 20 mg enteric tablet, 30**

14692G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	17.76	19.21	<sup>a</sup> APO-Esomeprazole [TY]	<sup>a</sup> Esomeprazole GH [GQ]
						<sup>a</sup> Esomeprazole GxP [AF]	<sup>a</sup> Esomeprazole RBX [RA]
						<sup>a</sup> Esomeprazole Viatris [MQ]	<sup>a</sup> ESOMEPRAZOLE-WGR [WG]
						<sup>a</sup> Esopreze [BG]	<sup>a</sup> Nexazole [RW]
						<sup>a</sup> Nexole [RF]	
			<sup>B</sup> 7.00	24.76	19.21	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

14701R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	1	..	17.76	19.21	<sup>a</sup> Noxicid Caps [AL]

■ **ESOMEPRAZOLE**

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15530**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**esomeprazole 20 mg enteric tablet, 30**

14444F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Esomeprazole [TY]	<sup>a</sup> Esomeprazole GH [GQ]
						<sup>a</sup> Esomeprazole GxP [AF]	<sup>a</sup> Esomeprazole RBX [RA]
						<sup>a</sup> Esomeprazole Viatris [MQ]	<sup>a</sup> ESOMEPRAZOLE-WGR [WG]
						<sup>a</sup> Esopreze [BG]	<sup>a</sup> Nexazole [RW]
						<sup>a</sup> Nexole [RF]	
			<sup>B</sup> 14.00	*36.07	23.52	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

14303T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> Noxicid Caps [AL]

■ **ESOMEPRAZOLE**

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)**

**15658**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****15682**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**esomeprazole 20 mg enteric tablet, 30**

14308C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 14.00	*36.07	23.52	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

14510Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> Noxicid Caps [AL]

**ESOMEPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 20 mg enteric tablet, 30**

12287Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 14.00	*36.07	23.52	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

12275C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 20 mg enteric tablet, 30**

14481E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 28.00	*58.67	31.60	<sup>a</sup> Nexium [AP]	

**esomeprazole 20 mg enteric capsule, 30**

14537D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A high dose proton pump inhibitor is: esomeprazole 40 mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** This authority approval must be sought by the specified specialist prescriber.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 40 mg enteric tablet, 30**

12283L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*28.07	29.52	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 14.00	*42.07	29.52	<sup>a</sup> Nexium [AP]	

**esomeprazole 40 mg enteric capsule, 30**

12290W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*28.07	29.52	<sup>a</sup> Noxicid Caps [AL]

**■ ESOMEPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A high dose proton pump inhibitor is: esomeprazole 40 mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** This authority approval must be sought by the specified specialist prescriber.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 40 mg enteric tablet, 30**

14512T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*42.67	31.60	<sup>a</sup> APO-Esomeprazole [TY] <sup>a</sup> Esomeprazole GxP [AF] <sup>a</sup> Esomeprazole Viatris [MQ] <sup>a</sup> Esopreze [BG] <sup>a</sup> Nexole [RF]	<sup>a</sup> Esomeprazole GH [GQ] <sup>a</sup> Esomeprazole RBX [RA] <sup>a</sup> ESOMEPRAZOLE-WGR [WG] <sup>a</sup> Nexazole [RW]
			<sup>B</sup> 28.00	*70.67	31.60	<sup>a</sup> Nexium [AP]	

**esomeprazole 40 mg enteric capsule, 30**

14445G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*42.67	31.60	<sup>a</sup> Noxicid Caps [AL]

■ **LANSOPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**lansoprazole 15 mg enteric capsule, 30**

8198L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	Zopral [AF]

**lansoprazole 15 mg orally disintegrating tablet, 28**

9331D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.14	18.59	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 4.80	21.94	18.59	<sup>a</sup> Zoton FasTabs [PF]	

■ **LANSOPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lansoprazole 15 mg enteric capsule, 30**

14448K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	Zopral [AF]

**lansoprazole 15 mg orally disintegrating tablet, 28**

14374M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.83	22.28	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 9.60	*30.43	22.28	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)****8780**

Scleroderma oesophagus

**lansoprazole 30 mg enteric capsule, 28**

2241Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**lansoprazole 30 mg orally disintegrating tablet, 28**

9478W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 4.68	22.44	19.21	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)****15658**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lansoprazole 30 mg enteric capsule, 28**

14340R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**lansoprazole 30 mg orally disintegrating tablet, 28**

14342W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 9.36	*31.43	23.52	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**lansoprazole 30 mg enteric capsule, 28**

11669E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**lansoprazole 30 mg orally disintegrating tablet, 28**

11697P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 4.68	22.44	19.21	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15530**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**lansoprazole 30 mg enteric capsule, 28**

14302R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**lansoprazole 30 mg orally disintegrating tablet, 28**

14406F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 9.36	*31.43	23.52	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8775**

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority required (STREAMLINED)****8774**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**lansoprazole 30 mg enteric capsule, 28**

2240X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]



**lansoprazole 30 mg orally disintegrating tablet, 28**

9477T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.76	19.21	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 4.68	22.44	19.21	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**lansoprazole 30 mg enteric capsule, 28**

12284M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

**lansoprazole 30 mg orally disintegrating tablet, 28**

12276D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 9.36	*31.43	23.52	<sup>a</sup> Zoton FasTabs [PF]	

**■ LANSOPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

#### **Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

#### **lansoprazole 30 mg enteric capsule, 28**

14304W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> APO-Lansoprazole [TX] <sup>a</sup> Zopral [AF]	<sup>a</sup> Lanzopran [RA]

#### **lansoprazole 30 mg orally disintegrating tablet, 28**

14339Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> APO-Lansoprazole ODT [TX] <sup>a</sup> Zopral ODT [AF]	<sup>a</sup> Lansoprazole ODT GH [GQ]
			<sup>B</sup> 18.72	*49.39	31.60	<sup>a</sup> Zoton FasTabs [PF]	

### ■ OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

#### **Restricted benefit**

Gastro-oesophageal reflux disease

#### **omeprazole 10 mg enteric tablet, 30**

14702T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	17.22	18.67	Losec Tablets [PB]

NP MW

### ■ OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

#### **Restricted benefit**

Scleroderma oesophagus

#### **Restricted benefit**

Zollinger-Ellison syndrome

#### **omeprazole 10 mg enteric tablet, 30**

8332M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	17.22	18.67	Losec Tablets [PB]

NP

### ■ OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

#### **Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Zollinger-Ellison syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**omeprazole 10 mg enteric tablet, 30**

14432N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	Losec Tablets [PB]

■ **OMEPRAZOLE**

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

**8780**

Scleroderma oesophagus

**Authority required (STREAMLINED)**

**8866**

Zollinger-Ellison syndrome

**omeprazole 20 mg enteric tablet, 30**

8333N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric tablet, 30**

9110L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>B</sup> 7.15	24.91	19.21	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric capsule, 30**

1327W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

■ **OMEPRAZOLE**

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

**15658**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)**

**15678**

Zollinger-Ellison syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**omeprazole 20 mg enteric tablet, 30**

14364B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric tablet, 30**

14397R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>B</sup> 14.30	*36.37	23.52	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric capsule, 30**

14559G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ OMEPRAZOLE**

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**omeprazole 20 mg enteric tablet, 30**

11677N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>B</sup> 7.15	24.91	19.21	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric tablet, 30**

11683X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric capsule, 30**

11682W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ OMEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8775**

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**omeprazole 20 mg enteric tablet, 30**

8331L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric tablet, 30**

9109K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	17.76	19.21	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>b</sup> 7.15	24.91	19.21	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric capsule, 30**

1326T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ OMEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8774**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**omeprazole 20 mg enteric tablet, 30**

14707C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	17.76	19.21	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>b</sup> 7.15	24.91	19.21	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric tablet, 30**

14708D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric capsule, 30**

14706B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	17.76	19.21	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ OMEPRAZOLE**

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15530**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**omeprazole 20 mg enteric tablet, 30**

14533X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]

**omeprazole 20 mg enteric tablet, 30**

14557E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>B</sup> 14.30	*36.37	23.52	<sup>a</sup> Losec Tablets [PB]	

**omeprazole 20 mg enteric capsule, 30**

14464G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ OMEPRAZOLE**

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**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**omeprazole 20 mg enteric tablet, 30**

12270T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> Acimax Tablets [FJ]	<sup>a</sup> Omepral [FQ]

						<sup>a</sup> Omeprazole Sandoz [SZ]	
			<sup>B</sup> 14.30	*36.37	23.52	<sup>a</sup> Losec Tablets [PB]	
<b>omeprazole 20 mg enteric tablet, 30</b>							
12272X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE-WGR [WG]	<sup>a</sup> Maxor EC Tabs [AF] <sup>a</sup> Ozmepr [RW]
<b>omeprazole 20 mg enteric capsule, 30</b>							
12281J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*22.07	23.52	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

## ■ OMEPRAZOLE

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**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

### Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

## omeprazole 20 mg enteric tablet, 30

14363Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> Acimax Tablets [FJ] <sup>a</sup> Omeprazole Sandoz [SZ]	<sup>a</sup> Omepral [FQ]
			<sup>B</sup> 28.60	*59.27	31.60	<sup>a</sup> Losec Tablets [PB]	

## omeprazole 20 mg enteric tablet, 30

14558F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> APO-Omeprazole [TX]	<sup>a</sup> Maxor EC Tabs [AF]

<sup>a</sup> OMEPRAZOLE-WGR [WG]<sup>a</sup> Ozmep [RW]**omeprazole 20 mg enteric capsule, 30**

14465H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	<sup>a</sup> APO-Omeprazole [TX] <sup>a</sup> OMEPRAZOLE CAPS WGR [WG] <sup>a</sup> Pemzo [RW] <sup>a</sup> Probitor [SZ]	<sup>a</sup> Maxor [AF] <sup>a</sup> Omeprazole Sandoz [HX] <sup>a</sup> Pharmacor Omeprazole 20 [CR]

**■ PANTOPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**pantoprazole 20 mg enteric tablet, 30**

8399C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG]  <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY]  <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> NOUMED PANTOPRAZOLE [VO]  <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]

**■ PANTOPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Zollinger-Ellison syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pantoprazole 20 mg enteric tablet, 30**

14501F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG]  <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY]  <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> NOUMED PANTOPRAZOLE [VO]  <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]

**■ PANTOPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Authority required (STREAMLINED)****8780**

Scleroderma oesophagus



**Authority required (STREAMLINED)****8866**

Zollinger-Ellison syndrome

**pantoprazole 40 mg enteric coated granules, 30 sachets**

9424B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	34.58	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

8008L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.55	18.00	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

**■ PANTOPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Authority required (STREAMLINED)****15658**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****15678**

Zollinger-Ellison syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

14466J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*55.71	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

14330F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.65	21.10	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

**■ PANTOPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

11678P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	34.58	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

11681T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.55	18.00	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

**■ PANTOPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15530**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

14500E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*55.71	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

14362X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.65	21.10	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

**■ PANTOPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8775**

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority required (STREAMLINED)****8774**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

9423Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	34.58	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

8007K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	16.55	18.00	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

**■ PANTOPRAZOLE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

12282K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*55.71	31.60	Somac [NQ]

**pantoprazole 40 mg enteric tablet, 30**

12277E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*19.65	21.10	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ]

<sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Salpraz [AF]  
<sup>a</sup> Somac [NQ] <sup>a</sup> Sozol [RW]

## ■ PANTOPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

### **Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### **pantoprazole 40 mg enteric coated granules, 30 sachets**

14395P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*97.95	31.60	Somac [NQ]

### **pantoprazole 40 mg enteric tablet, 30**

14394N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*25.83	27.28	<sup>a</sup> APO-Pantoprazole [TX] <sup>a</sup> BTC Pantoprazole [BG] <sup>a</sup> NOUMED PANTOPRAZOLE [VO] <sup>a</sup> Panthron [ZS] <sup>a</sup> Pantoprazole generichealth [HQ] <sup>a</sup> PANTOPRAZOLE-WGR [WG] <sup>a</sup> Somac [NQ]	<sup>a</sup> APX-PANTOPRAZOLE [TW] <sup>a</sup> I-Pantoprazole [CR] <sup>a</sup> Ozpan [RA] <sup>a</sup> Pantoprazole APOTEX [TY] <sup>a</sup> Pantoprazole Sandoz [SZ] <sup>a</sup> Salpraz [AF] <sup>a</sup> Sozol [RW]

## ■ RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

### **Restricted benefit**

Gastro-oesophageal reflux disease

### **Restricted benefit**

Scleroderma oesophagus

**rabeprazole sodium 10 mg enteric tablet, 28**

8507R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.04	18.49	<sup>a</sup> APO-Rabeprazole [TX]	<sup>a</sup> Parbezol [RW]
						<sup>a</sup> Rabeprazole Sandoz [SZ]	<sup>a</sup> RABEPRAZOLE-WGR [WG]
						<sup>a</sup> Pariet [JC]	
			<sup>B</sup> 5.01	22.05	18.49		

**■ RABEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**rabeprazole sodium 10 mg enteric tablet, 28**

14502G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.63	22.08	<sup>a</sup> APO-Rabeprazole [TX]	<sup>a</sup> Parbezol [RW]
						<sup>a</sup> Rabeprazole Sandoz [SZ]	<sup>a</sup> RABEPRAZOLE-WGR [WG]
						<sup>a</sup> Pariet [JC]	
			<sup>B</sup> 10.02	*30.65	22.08		

**■ RABEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

**8780**

Scleroderma oesophagus

**rabeprazole sodium 20 mg enteric tablet, 30**

8508T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.04	18.49	<sup>a</sup> APO-Rabeprazole [TX]	<sup>a</sup> Noumed Rabeprazole [VO]
						<sup>a</sup> Parbezol [RW]	<sup>a</sup> Rabeprazole Mylan [AF]
						<sup>a</sup> Rabeprazole Sandoz [SZ]	<sup>a</sup> Rabeprazole SUN [RN]
						<sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Zabep [AL]
						<sup>a</sup> Pariet [JC]	
			<sup>B</sup> 5.01	22.05	18.49		

**■ RABEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

**15658**

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**rabeprazole sodium 20 mg enteric tablet, 30**

14433P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.63	22.08	<sup>a</sup> APO-Rabeprazole [TX]	<sup>a</sup> Noumed Rabeprazole [VO]
						<sup>a</sup> Parbezol [RW]	<sup>a</sup> Rabeprazole Mylan [AF]
						<sup>a</sup> Rabeprazole Sandoz [SZ]	<sup>a</sup> Rabeprazole SUN [RN]
						<sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Zabep [AL]
						<sup>a</sup> Pariet [JC]	
			<sup>B</sup> 10.02	*30.65	22.08		

**■ RABEPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**rabeprazole sodium 20 mg enteric tablet, 30**

11670F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.04	18.49	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Noumed Rabeprazole [VO] <sup>a</sup> Rabeprazole Mylan [AF] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Zabep [AL]
			<sup>B</sup> 5.01	22.05	18.49	<sup>a</sup> Pariet [JC]	

**■ RABEPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****15530**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**rabeprazole sodium 20 mg enteric tablet, 30**

14463F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.63	22.08	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Noumed Rabeprazole [VO] <sup>a</sup> Rabeprazole Mylan [AF] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Zabep [AL]
			<sup>B</sup> 10.02	*30.65	22.08	<sup>a</sup> Pariet [JC]	

**■ RABEPRAZOLE****Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****8775**

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority required (STREAMLINED)****8774**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**rabeprazole sodium 20 mg enteric tablet, 30**

8509W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.04	18.49	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Noumed Rabeprazole [VO] <sup>a</sup> Rabeprazole Mylan [AF] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Zabep [AL]
			<sup>B</sup> 5.01	22.05	18.49	<sup>a</sup> Pariet [JC]	

## ■ RABEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

### **Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### **rabeprazole sodium 20 mg enteric tablet, 30**

12286P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*20.63	22.08	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Noumed Rabeprazole [VO] <sup>a</sup> Rabeprazole Mylan [AF] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Zabep [AL]
			<sup>B</sup> 10.02	*30.65	22.08	<sup>a</sup> Pariet [JC]	

## ■ RABEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR

- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**rabeprazole sodium 20 mg enteric tablet, 30**

14396Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*27.79	29.24	<sup>a</sup> APO-Rabeprazole [TX] <sup>a</sup> Parbezol [RW] <sup>a</sup> Rabeprazole Sandoz [SZ] <sup>a</sup> RABEPRAZOLE-WGR [WG]	<sup>a</sup> Noumed Rabeprazole [VO] <sup>a</sup> Rabeprazole Mylan [AF] <sup>a</sup> Rabeprazole SUN [RN] <sup>a</sup> Zabep [AL]
			<sup>B</sup> 20.04	*47.83	29.24	<sup>a</sup> Pariet [JC]	

**Combinations for eradication of *Helicobacter pylori*****■ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN**

**Note** Pharmaceutical benefits that have the form pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) and pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Eradication of *Helicobacter pylori*

**Clinical criteria:**

- The condition must be associated with peptic ulcer disease.

**esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack**

10759G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	35.71	31.60	<sup>a</sup> ESOMEPRAZOLE SANDOZ Hp7 [SZ]

**esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack**

8738X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	<sup>B</sup> 4.33	40.04	31.60	<sup>a</sup> Nexium Hp7 [AP]

**■ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS****BELLADONNA AND DERIVATIVES, PLAIN**

*Belladonna alkaloids, tertiary amines*

**■ ATROPINE SULFATE****atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

1089H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	29.45	30.90	Atropine Injection (Bridgewest) [WZ]

**atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

5022H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	29.45	30.90	Atropine Injection (Bridgewest) [WZ]

**PROPULSIVES**

*Propulsives*



## ■ DOMPERIDONE

## domperidone 10 mg tablet, 25

1347X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	15.72	17.17	<sup>a</sup> APO-DOMPERIDONE [TX]	<sup>a</sup> Motilium [JT]

## ■ METOCLOPRAMIDE

## metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

1206L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	21.09	22.54	<sup>a</sup> Metoclopramide HCl Medsurge [DZ]	<sup>a</sup> METOCLOPRAMIDE INJECTION BP [WZ]

## metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

5153F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	21.09	22.54	<sup>a</sup> Metoclopramide HCl Medsurge [DZ]	<sup>a</sup> METOCLOPRAMIDE INJECTION BP [WZ]

## metoclopramide hydrochloride 10 mg tablet, 25

1207M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	16.15	17.60	<sup>a</sup> APO-Metoclopramide [TX] <sup>a</sup> METOCLOPRAMIDE-WGR [WG]	<sup>a</sup> EMEXLON [RW] <sup>a</sup> Pramin [AF]
			<sup>B</sup> 3.55	19.70	17.60	<sup>a</sup> Maxolon [IL]	

## metoclopramide hydrochloride 10 mg tablet, 25

5151D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.15	17.60	<sup>a</sup> APO-Metoclopramide [TX] <sup>a</sup> METOCLOPRAMIDE-WGR [WG]	<sup>a</sup> EMEXLON [RW] <sup>a</sup> Pramin [AF]
			<sup>B</sup> 3.55	19.70	17.60	<sup>a</sup> Maxolon [IL]	

## ■ ANTIEMETICS AND ANTINAUSEANTS

## ANTIEMETICS AND ANTINAUSEANTS

*Serotonin (5HT<sub>3</sub>) antagonists*

## ■ FOSNETUPITANT + PALONOSETRON

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Nausea and vomiting

**Clinical criteria:**

- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy, **AND**
- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- Patient must be unable to swallow; OR
- Patient must be contraindicated to oral anti-emetics.

## fosnetupitant 235 mg + palonosetron 250 microgram injection, 1 vial

13640X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	111.59	31.60	Akynzeo IV [JZ]

## ■ GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.
- Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

## granisetron 3 mg/3 mL injection, 3 mL ampoule

8729K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.37	17.82	<sup>a</sup> Granisetron-AFT [AE]	<sup>a</sup> Kytril [IX]

## ■ GRANISETRON

Authority required (STREAMLINED)**4092**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy.

**granisetron 3 mg/3 mL injection, 3 mL ampoule**

8730L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.37	17.82	<sup>a</sup> Granisetron-AFT [AE]	<sup>a</sup> Kytril [IX]

## ■ GRANISETRON

Authority required (STREAMLINED)**10498**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with oral chemotherapy being used to treat malignancy.

**granisetron 2 mg tablet, 5**

8873B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	58.03	31.60	Kytril [IX]

## ■ GRANISETRON

Restricted benefit

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

**granisetron 2 mg tablet, 1**

8728J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*31.29	31.60	Kytril [IX]

## ■ NETUPITANT + PALONOSETRON

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.**Note** Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.**Note** No increase in the maximum number of repeats may be authorised.Authority required (STREAMLINED)**14443**

Nausea and vomiting

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.

**netupitant 300 mg + palonosetron 500 microgram capsule, 1**

10731T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	101.26	31.60	Akynzeo [JZ]

## ■ ONDANSETRON

Authority required (STREAMLINED)**15193**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

**ondansetron 4 mg tablet, 10**

1594X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22.87	24.32	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ] <sup>a</sup> Ondansetron SZ [HX]	<sup>a</sup> APX-Ondansetron [TY] <sup>a</sup> Ondansetron Mylan Tablets [AF] <sup>a</sup> Ondansetron Tablets Viatris [AL]

<sup>a</sup> ONDANSETRON-WGR [WG] <sup>a</sup> Zofran [AS]  
<sup>a</sup> Zotren 4 [RF]

**ondansetron 8 mg tablet, 10**

1595Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.10	26.55	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ]  <sup>a</sup> Ondansetron SZ [HX]  <sup>a</sup> ONDANSETRON-WGR [WG] <sup>a</sup> Zotren 8 [RF]	<sup>a</sup> APX-Ondansetron [TY] <sup>a</sup> Ondansetron Mylan Tablets [AF] <sup>a</sup> Ondansetron Tablets Viatris [AL]  <sup>a</sup> Zofran [AS]

**ondansetron 4 mg/5 mL oral liquid, 50 mL**

8233H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	1	..	100.31	31.60	Zofran syrup 50 mL [AS]

**■ ONDANSETRON****Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

**ondansetron 8 mg orally disintegrating tablet, 4**

5471Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	18.20	19.65	<sup>a</sup> APX-Ondansetron ODT [TY] <sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> ONDANSETRON ODT-WGR [WG] <sup>a</sup> Zotren ODT [RF]	<sup>a</sup> Ondansetron Mylan ODT [AF] <sup>a</sup> Ondansetron ODT Viatris [AL] <sup>a</sup> Ondansetron SZ ODT [HX]

**ondansetron 4 mg orally disintegrating tablet, 4**

5470X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.37	18.82	<sup>a</sup> APX-Ondansetron ODT [TY] <sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> ONDANSETRON ODT-WGR [WG] <sup>a</sup> Zotren ODT [RF]	<sup>a</sup> Ondansetron Mylan ODT [AF] <sup>a</sup> Ondansetron ODT Viatris [AL] <sup>a</sup> Ondansetron SZ ODT [HX]

**■ ONDANSETRON****Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

**ondansetron 4 mg tablet, 4**

8224W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.37	18.82	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ]  <sup>a</sup> Ondansetron SZ [HX]  <sup>a</sup> ONDANSETRON-WGR [WG] <sup>a</sup> Zotren 4 [RF]	<sup>a</sup> APX-Ondansetron [TY] <sup>a</sup> Ondansetron Mylan Tablets [AF] <sup>a</sup> Ondansetron Tablets Viatris [AL]  <sup>a</sup> Zofran [AS]

**ondansetron 8 mg tablet, 4**

8225X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	18.20	19.65	<sup>a</sup> APO-Ondansetron [TX] <sup>a</sup> Ondansetron-DRLA [RZ]  <sup>a</sup> Ondansetron SZ [HX]  <sup>a</sup> ONDANSETRON-WGR [WG] <sup>a</sup> Zotren 8 [RF]	<sup>a</sup> APX-Ondansetron [TY] <sup>a</sup> Ondansetron Mylan Tablets [AF] <sup>a</sup> Ondansetron Tablets Viatris [AL]  <sup>a</sup> Zofran [AS]

**■ ONDANSETRON****Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

### ondansetron 4 mg/5 mL oral liquid, 50 mL

9441X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	100.31	31.60	Zofran syrup 50 mL [AS]

## ■ ONDANSETRON

**Note** Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.

### Authority required (STREAMLINED)

15193

Nausea and vomiting

### Clinical criteria:

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

### ondansetron 4 mg orally disintegrating tablet, 10

5472B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.87	24.32	<sup>a</sup> APX-Ondansetron ODT [TY] <sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron ODT Viatris [AL] <sup>a</sup> Ondansetron SZ ODT [HX]	<sup>a</sup> Ondansetron Mylan ODT [AF] <sup>a</sup> Ondansetron ODT Lupin [HQ] <sup>a</sup> ONDANSETRON ODT-WGR [WG] <sup>a</sup> Zotren ODT [RF]

### ondansetron 4 mg wafer, 10

8412R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	<sup>B</sup> 3.46	26.33	24.32	<sup>a</sup> Zofran Zydis [AS]

## ■ ONDANSETRON

**Note** Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

### Authority required (STREAMLINED)

15193

Nausea and vomiting

### Clinical criteria:

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

### ondansetron 8 mg orally disintegrating tablet, 10

5473C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.10	26.55	<sup>a</sup> APX-Ondansetron ODT [TY] <sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron ODT Viatris [AL] <sup>a</sup> Ondansetron SZ ODT [HX]	<sup>a</sup> Ondansetron Mylan ODT [AF] <sup>a</sup> Ondansetron ODT Lupin [HQ] <sup>a</sup> ONDANSETRON ODT-WGR [WG] <sup>a</sup> Zotren ODT [RF]

### ondansetron 8 mg wafer, 10

8413T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	<sup>B</sup> 3.45	31.30	29.30	<sup>a</sup> Zofran Zydis [AS]

## ■ PALONOSETRON

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** This drug is not PBS-subsidised for administration with oral 5-HT<sub>3</sub> antagonists.

### Restricted benefit

Nausea and vomiting

### Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

### palonosetron 250 microgram/5 mL injection, 5 mL vial

5295Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.12	25.57	<sup>a</sup> Palonosetron Dr.Reddy's [RZ]	<sup>a</sup> PALONOSETRON Medsurge [DZ]

*Other antiemetics*

## ■ APREPITANT

**Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4211**

Nausea and vomiting

#### **Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

### Authority required (STREAMLINED)

**4215**

Nausea and vomiting

#### **Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

### Authority required (STREAMLINED)

**6444**

Nausea and vomiting

#### **Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

### Authority required (STREAMLINED)

**6370**

Nausea and vomiting


#### **Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

### **aprepitant 165 mg capsule, 1**

2518M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	72.78	31.60	<sup>a</sup> Aprepitant APOTEX [TX]	<sup>a</sup> APREPITANT SCP [XC]

## ■ FOSAPREPITANT

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**6886**

Nausea and vomiting

#### **Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose

of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6891**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6887**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**Authority required (STREAMLINED)**

**6852**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**fosaprepitant 150 mg injection, 1 vial**

11107N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	87.90	31.60	<sup>a</sup> Emend IV [MK] <sup>a</sup> FOSAPREPITANT MEDSURGE [DZ]	<sup>a</sup> FOSAPREPITANT-AFT [AE] <sup>a</sup> FOSAPREPITANT MSN [RQ]

▪ **PROCHLORPERAZINE**

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules**

5206B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	23.78	25.23	Stemetil [IX]

**prochlorperazine maleate 5 mg tablet, 25**

5205Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.37	17.82	<sup>a</sup> APO-Prochlorperazine [TX] <sup>a</sup> Prochlorperazine GH [GQ]	<sup>a</sup> ProCalm [RW] <sup>a</sup> PROCHLORPERAZINE-WGR [WG]
			<sup>B</sup> 2.79	19.16	17.82	<sup>a</sup> Stemetil [IX]	

▪ **PROCHLORPERAZINE**

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**Note** As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

**prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules**

2369Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	23.78	25.23	Stemetil [IX]

**prochlorperazine maleate 5 mg tablet, 25**

2893G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.37	17.82	<sup>a</sup> APO-Prochlorperazine [TX]	<sup>a</sup> ProCalm [RW]
						<sup>a</sup> Prochlorperazine GH [GQ]	<sup>a</sup> PROCHLORPERAZINE-WGR [WG]
			<sup>B</sup> 2.79	19.16	17.82	<sup>a</sup> Stemetil [IX]	

**■ PROMETHAZINE****promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules**

3374N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*36.65	31.60	DBL Promethazine Hydrochloride [PF]

**■ BILE AND LIVER THERAPY****BILE THERAPY***Bile acids and derivatives***■ OBETICHOIC ACID**

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Authority required (STREAMLINED)****12138**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

**Clinical criteria:**

- Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.

The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records.

**obeticholic acid 5 mg tablet, 30**

12630R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	3793.60	31.60	Ocaliva [EU]

**obeticholic acid 10 mg tablet, 30**

12640G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	3793.60	31.60	Ocaliva [EU]

**■ OBETICHOIC ACID**

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note** In accordance with the dosing directions in the approved Product Information, the 10 mg presentation is not PBS listed for initiation of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Authority required**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR
- Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.

**Clinical criteria:**

- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR
- Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.

**Population criteria:**

- Patient must be aged 18 years or older.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

**obeticholic acid 5 mg tablet, 30**

12623J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3793.60	31.60	Ocaliva [EU]

▪ **URSODEOXYCHOLIC ACID**

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**9032**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

**ursodeoxycholic acid 250 mg capsule, 100**

8448P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*227.77	31.60	<sup>a</sup> APO-Ursodeoxycholic acid [TX]	<sup>a</sup> Ursodox GH [GQ]
						<sup>a</sup> Ursofalk [FD]	<sup>a</sup> Ursosan [BZ]

▪ **URSODEOXYCHOLIC ACID**

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form ursodeoxycholic acid 500 mg capsule and pharmaceutical benefits that have the form ursodeoxycholic acid 500 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**9032**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

**ursodeoxycholic acid 500 mg tablet, 100**

11180K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	4	..	296.35	31.60	<sup>a</sup> Ursofalk [FD]

**ursodeoxycholic acid 500 mg capsule, 100**

14716M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	4	..	296.35	31.60	<sup>a</sup> Ursodox GH [GQ]



## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

Contact laxatives

#### ■ BISACODYL

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- Patient must be receiving palliative care.

##### Restricted benefit

Terminal malignant neoplasia

##### Restricted benefit

Anorectal congenital abnormalities

##### Restricted benefit

Megacolon

#### bisacodyl 5 mg enteric tablet, 200

1259G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	19.90	21.35	Lax-Tab [AE]

#### ■ BISACODYL

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

##### Restricted benefit

Constipation

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

##### Restricted benefit

Terminal malignant neoplasia

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Anorectal congenital abnormalities

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Megacolon

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**bisacodyl 5 mg enteric tablet, 200**

14446H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*26.35	27.80	Lax-Tab [AE]

■ **BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 10**

1260H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*26.10	27.55	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			<sup>B</sup> 1.29	*27.39	27.55	<sup>a</sup> Dulcolax [VZ]

**bisacodyl 10 mg suppository, 12**

1258F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	4	..	*24.75	26.20	Petrus Bisacodyl Suppositories [PP]

■ **BISACODYL****Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 10**

14447J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	6	5	..	*38.73	31.60	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			<sup>B</sup> 2.58	*41.31	31.60	<sup>a</sup> Dulcolax [VZ]

**bisacodyl 10 mg suppository, 12**

14305X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	6	4	..	*36.03	31.60	Petrus Bisacodyl Suppositories [PP]

***Osmotically acting laxatives*****▪ MACROGOL-3350****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

3416T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.93	24.38	OsmoLax [KY]

**▪ MACROGOL-3350****Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

14341T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*32.41	31.60	OsmoLax [KY]

**▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE****Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets**

8612G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	19.73	21.18	<sup>a</sup> APOHEALTH Macrogol with Electrolytes [GX] <sup>a</sup> Chemists' Own Macrogol with Electrolytes [RW] <sup>a</sup> Molaxole [XT]	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES [TX] <sup>a</sup> Macrovic [RF]

## ▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets**

14408H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*26.01	27.46	<sup>a</sup> APOHEALTH Macrogol with Electrolytes [GX] <sup>a</sup> Chemists' Own Macrogol with Electrolytes [RW] <sup>a</sup> Molaxole [XT]	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES [TX] <sup>a</sup> Macrovic [RF]

## Enemas

## ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

2091C

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	2	..	*37.21	31.60	Micolette [AE]

NP

### ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

Terminal malignant neoplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Anorectal congenital abnormalities

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Megacolon

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL

14534Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	..	*60.95	31.60	Micolette [AE]

## ■ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### INTESTINAL ANTIINFECTIVES

#### Antibiotics

## ■ NYSTATIN

nystatin 500 000 units capsule, 50

1699K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.63	24.08	Nilstat [AS]

nystatin 500 000 units capsule, 50

3345C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.63	24.08	Nilstat [AS]

nystatin 500 000 units tablet, 50

1696G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.63	24.08	Nilstat [AS]

nystatin 500 000 units tablet, 50

3342X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.63	24.08	Nilstat [AS]

## ■ RIFAXIMIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Prevention of hepatic encephalopathy

#### Treatment criteria:

- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

#### Clinical criteria:

- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

rifaximin 550 mg tablet, 56

10001J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	453.43	31.60	Xifaxan [NE]

## ■ VANCOMYCIN

**Note** Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

#### Authority required

Antibiotic associated pseudomembranous colitis

#### Clinical criteria:

- The condition must be due to **Clostridium difficile**, **AND**
- The condition must be unresponsive to metronidazole.

#### Authority required

Antibiotic associated pseudomembranous colitis

#### Clinical criteria:

- The condition must be due to **Clostridium difficile**, **AND**
- Patient must have an intolerance to metronidazole.

vancomycin 125 mg capsule, 20

3113W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*108.43	31.60	<sup>a</sup> Vancocin [AS]	<sup>a</sup> Vancomycin BNM 125mg [BZ]

vancomycin 250 mg capsule, 20

3114X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*207.83	31.60	<sup>a</sup> Vancocin [AS]	<sup>a</sup> Vancomycin BNM 250mg [BZ]

## ELECTROLYTES WITH CARBOHYDRATES

### Oral rehydration salt formulations

## ■ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

3196F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	18.27	19.72	O.R.S. [XT]

## ■ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

### Authority required

Rehydration in intestinal failure

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

11049M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	30	..	..	*159.87	31.60	O.R.S. [XT]

## ANTIPROPULSIVES

### *Antipropulsives*

## ■ DIPHENOXYLATE + ATROPINE SULFATE

**diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20**

2501P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.37	17.82	<sup>a</sup> Lofenoxal [IL]
			<sup>B</sup> 3.33	19.70	17.82	<sup>a</sup> Lomotil [IM]

## ■ LOPERAMIDE

### Authority required (STREAMLINED)

**6364**

Diarrhoea

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**loperamide hydrochloride 2 mg capsule, 12**

1571Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	14.95	16.40	<sup>a</sup> Gastrex [CR]	<sup>a</sup> Gastro-Stop [AS]

## ■ LOPERAMIDE

### Authority required

Diarrhoea

**loperamide hydrochloride 2 mg capsule, 12**

10889D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*20.92	22.37	<sup>a</sup> Gastrex [CR]	<sup>a</sup> Gastro-Stop [AS]

## INTESTINAL ANTIINFLAMMATORY AGENTS

### *Corticosteroids acting locally*

## ■ BUDESONIDE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**budesonide 2 mg/application foam, 2 x 14 applications**

10034D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	151.92	31.60	Budenofalk [FD]

## ■ BUDESONIDE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**12607**

Mild to moderate Crohn disease

**Clinical criteria:**



- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 12 weeks in any single course.

### budesonide 3 mg modified release capsule, 90

12915R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	55.23	31.60	Entocort [EU]

NP

## ■ BUDESONIDE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

15772

Mild to moderate Crohn disease

### Clinical criteria:

- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 10 weeks in any single course.

### budesonide 3 mg enteric capsule, 50

14571X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*67.61	31.60	Budenofalk [FD]

NP

## ■ BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Eosinophilic oesophagitis

Treatment Phase: Subsequent continuing treatment - Maintenance of remission

### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm<sup>2</sup> hpf on oesophageal biopsy,

### AND

- The condition must not have progressed while being treated with this drug.

### Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

### budesonide 500 microgram orally disintegrating tablet, 60

12987M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	414.88	31.60	Jorveza [FD]

### budesonide 1 mg orally disintegrating tablet, 60

12982G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	414.88	31.60	Jorveza [FD]

## ■ BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment - Induction of remission

### Clinical criteria:

- Patient must have a history of symptoms of oesophageal dysfunction, **AND**
- Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm<sup>2</sup> hpf, **AND**
- Patient must not receive more than 90 days of treatment under this restriction.

### Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis.

Applications for treatment of this condition must be received within 12 weeks of biopsy.

Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation.

Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy.

The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.

### **budesonide 1 mg orally disintegrating tablet, 90**

12994X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	618.10	31.60	Jorveza [FD]

## ■ BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Eosinophilic oesophagitis

Treatment Phase: First continuing treatment - until remission is confirmed

### Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 36 weeks of treatment under this restriction.

### Treatment criteria:

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

### **budesonide 500 microgram orally disintegrating tablet, 60**

13719C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	414.88	31.60	Jorveza [FD]

**budesonide 1 mg orally disintegrating tablet, 60**

13711P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	414.88	31.60	Jorveza [FD]

**■ PREDNISOLONE SODIUM PHOSPHATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL**

1920C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*182.51	31.60	Predsol [AS]

**■ PREDNISOLONE SODIUM PHOSPHATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**prednisolone (as sodium phosphate) 5 mg suppository, 10**

2554K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*40.77	31.60	Predsol [AS]

***Aminosalicylic acid and similar agents*****■ BALSALAZIDE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**7621**

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 280**

11351K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	158.43	31.60	Colazide [PK]

**■ BALSALAZIDE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14306**

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

**balsalazide sodium 750 mg capsule, 280**

13484Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*308.41	31.60	Colazide [PK]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Ulcerative colitis

**mesalazine 4 g modified release granules, 30 sachets**

10254Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	129.37	31.60	Pentasa [FP]

**mesalazine 3 g modified release granules, 30 sachets**

10257W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	101.66	31.60	Salofalk [FD]

**mesalazine 800 mg enteric tablet, 90**

11210B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	79.11	31.60	Asacol [EU]

**mesalazine 1 g modified release granules, 100 sachets**

8599N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	115.65	31.60	Salofalk [FD]

**mesalazine 1.6 g enteric tablet, 60**

12463Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*153.69	31.60	Asacol [EU]

**mesalazine 1.5 g modified release granules, 60 sachets**

9206M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	101.66	31.60	Salofalk [FD]

**mesalazine 500 mg modified release granules, 100 sachets**

8598M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*123.13	31.60	Salofalk [FD]

**■ MESALAZINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Ulcerative colitis

**Restricted benefit**

Crohn disease

**mesalazine 1 g enteric tablet, 60**

11554D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*137.75	31.60	Salofalk [FD]

**mesalazine 1 g modified release granules, 100 sachets**

12203G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	106.97	31.60	Pentasa [FP]

**mesalazine 2 g modified release granules, 60 sachets**

2287J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	129.37	31.60	Pentasa [FP]

**mesalazine 1 g modified release tablet, 60**

3413P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*137.09	31.60	Pentasa [FP]

**mesalazine 250 mg enteric tablet, 100**

1611T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	45.10	31.60	Mesasal [GO]

**mesalazine 500 mg enteric tablet, 100**

8731M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*123.13	31.60	Salofalk [FD]

**mesalazine 500 mg modified release tablet, 100**

2214M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*123.13	31.60	Pentasa [FP]

**■ MESALAZINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Crohn disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mesalazine 1 g enteric tablet, 60**

13394Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*267.07	31.60	Salofalk [FD]

**mesalazine 1 g modified release granules, 100 sachets**

13355X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*204.83	31.60	Pentasa [FP]

**mesalazine 2 g modified release granules, 60 sachets**

13397D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*250.27	31.60	Pentasa [FP]

**mesalazine 1 g modified release tablet, 60**

13576M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*265.71	31.60	Pentasa [FP]

**mesalazine 250 mg enteric tablet, 100**

13423L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*76.75	31.60	Mesasal [GO]

**mesalazine 500 mg enteric tablet, 100**

13362G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*237.79	31.60	Salofalk [FD]

**mesalazine 500 mg modified release tablet, 100**

13396C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*237.79	31.60	Pentasa [FP]

**■ MESALAZINE****Note** Not for the treatment of Crohn disease**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mesalazine 4 g modified release granules, 30 sachets**

13456F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*250.27	31.60	Pentasa [FP]

**mesalazine 3 g modified release granules, 30 sachets**

13518L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*193.69	31.60	Salofalk [FD]

**mesalazine 800 mg enteric tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13422K	2	5	..	*146.33	31.60	Asacol [EU]

**mesalazine 1 g modified release granules, 100 sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13398E	2	5	..	*222.85	31.60	Salofalk [FD]

**mesalazine 1.6 g enteric tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13395B	4	4	..	*298.95	31.60	Asacol [EU]

**mesalazine 1.5 g modified release granules, 60 sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13460K	2	5	..	*193.69	31.60	Salofalk [FD]

**mesalazine 500 mg modified release granules, 100 sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13361F	4	5	..	*237.79	31.60	Salofalk [FD]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

Ulcerative colitis

**mesalazine 1.2 g modified release tablet, 120**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13247F	1	5	..	173.58	31.60	<sup>a</sup> MESALZ [RA]

**mesalazine 1.2 g modified release tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9353G	2	5	..	*173.59	31.60	<sup>a</sup> Mesalazine 1.2 TAKEDA [NQ]	<sup>a</sup> Mezavant [TK]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mesalazine 1.2 g modified release tablet, 120**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13356Y	2	5	..	*338.71	31.60	<sup>a</sup> MESALZ [RA]

**mesalazine 1.2 g modified release tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13487W	4	5	..	*338.71	31.60	<sup>a</sup> Mesalazine 1.2 TAKEDA [NQ]	<sup>a</sup> Mezavant [TK]

**■ MESALAZINE**

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

#### **mesalazine 1 g suppository, 30**

5461K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	99.83	31.60	Salofalk [FD]

#### **mesalazine 1 g suppository, 28**

12198B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	83.13	31.60	Pentasa [FP]

### ▪ MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**4888**

Acute episode of mild to moderate ulcerative colitis

#### **mesalazine 1 g/100 mL enema, 7 x 100 mL**

8753Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*215.27	31.60	Pentasa [FP]

#### **mesalazine 2 g/60 mL enema, 7 x 60 mL**

8616L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*215.27	31.60	Salofalk [FD]

#### **mesalazine 4 g/60 mL enema, 7 x 60 mL**

8617M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*331.99	31.60	Salofalk [FD]

#### **mesalazine 1 g/application foam, 14 applications**

8768L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*247.83	31.60	Salofalk [FD]

### ▪ OLSALAZINE

**Note** Not for the treatment of Crohn disease

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**4824**

Ulcerative colitis

#### **Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

#### **olsalazine sodium 250 mg capsule, 100**

1728Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	45.05	31.60	Dipentum [IX]

#### **olsalazine sodium 500 mg tablet, 100**

8086N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	69.10	31.60	Dipentum [IX]

### ▪ SULFASALAZINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sulfasalazine 500 mg tablet, 100**

2093E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*52.83	31.60	Salazopyrin [PF]

**sulfasalazine 500 mg enteric tablet, 100**

2096H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*56.81	31.60	<sup>a</sup> Pyralin EN [FZ]
			<sup>B</sup> 4.00	*60.81	31.60	<sup>a</sup> Salazopyrin-EN [PF]

**■ SULFASALAZINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sulfasalazine 500 mg tablet, 100**

13557M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*92.19	31.60	Salazopyrin [PF]

**sulfasalazine 500 mg enteric tablet, 100**

13433B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*100.15	31.60	<sup>a</sup> Pyralin EN [FZ]
			<sup>B</sup> 8.00	*108.15	31.60	<sup>a</sup> Salazopyrin-EN [PF]

**■ DIGESTIVES, INCL. ENZYMES****DIGESTIVES, INCL. ENZYMES***Enzyme preparations***■ PANCREATIC EXTRACT****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**pancreatic extract 10 000 units modified release capsule, 100**

8020D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	10	..	*145.92	31.60	Creon 10,000 [GO]

**pancreatic extract 25 000 units modified release capsule, 100**

8021E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*118.03	31.60	Creon 25,000 [GO]

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

5453B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	10	..	*113.43	31.60	Creon Micro [GO]

**pancreatic extract 35 000 units modified release capsule, 100**

12595X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*161.85	31.60	Creon 35,000 [GO]

**■ PANCREATIC EXTRACT****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pancreatic extract 10 000 units modified release capsule, 100**

13560Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	10	..	*283.37	31.60	Creon 10,000 [GO]



**pancreatic extract 25 000 units modified release capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13470Y	4	10	..	*227.63	31.60	Creon 25,000 [GO]

NP

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13375Y	6	10	..	*218.37	31.60	Creon Micro [GO]

NP

**pancreatic extract 35 000 units modified release capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13407P	4	10	..	*315.23	31.60	Creon 35,000 [GO]

NP

**DRUGS USED IN DIABETES****INSULINS AND ANALOGUES***Insulins and analogues for injection, fast-acting***INSULIN ASPART****insulin aspart 100 units/mL fast acting injection, 5 x 3 mL cartridges**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13651L	5	1	..	*167.52	31.60	Fiasp Penfill [NO]

NP

**insulin aspart 100 units/mL injection, 1 x 10 mL vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8571D	5	2	..	*101.27	31.60	NovoRapid [NO]

NP

**insulin aspart 100 units/mL injection, 5 x 3 mL cartridges**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8435Y	5	1	..	*167.52	31.60	NovoRapid Penfill 3 mL [NO]

NP

**insulin aspart 100 units/mL injection, 5 x 3 mL pen devices**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12254Y	5	1	..	*167.52	31.60	NovoRapid FlexPen [NF]

NP

**INSULIN GLULISINE****insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12268Q	5	1	..	*167.57	31.60	Apidra SoloStar [SW]

NP

**insulin glulisine 100 units/mL injection, 1 x 10 mL vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9224L	5	2	..	*101.27	31.60	Apidra [SW]

NP

**insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1921D	5	1	..	*167.57	31.60	Apidra [AV]

NP

**INSULIN LISPRO****insulin lispro 200 units/mL injection, 5 x 3 mL pen devices**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11645X	5	1	..	*266.87	31.60	Humalog U200 Kwikpen [LY]

NP

**insulin lispro 100 units/mL injection, 5 x 3 mL pen devices**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12237C	5	1	..	*167.52	31.60	Humalog KwikPen [KP]

NP

**insulin lispro 100 units/mL injection, 1 x 10 mL vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8084L	5	2	..	*101.27	31.60	Humalog [LY]

NP

**insulin lispro 100 units/mL injection, 5 x 3 mL cartridges**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8212F	5	1	..	*167.52	31.60	Humalog [LY]

NP

■ **INSULIN NEUTRAL HUMAN****insulin neutral human 100 units/mL injection, 1 x 10 mL vial**

1531N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	2	..	*86.57	31.60	Actrapid [NO]	Humulin R [LY]

**insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges**

1762R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*141.07	31.60	Actrapid Penfill 3 mL [NO]	Humulin R [LY]

*Insulins and analogues for injection, intermediate-acting*■ **INSULIN ISOPHANE HUMAN****insulin isophane human 100 units/mL injection, 1 x 10 mL vial**

1533Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	2	..	*86.57	31.60	Humulin NPH [LY]	Protaphane [NO]

**insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges**

1761Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*141.07	31.60	Humulin NPH [LY]	Protaphane Penfill 3 mL [NO]

*Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting*■ **INSULIN ASPART + INSULIN ASPART PROTAMINE****insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges**

8609D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	NovoMix 30 Penfill 3 mL [NO]

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices**

12238D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	NovoMix 30 FlexPen [NF]

■ **INSULIN DEGLUDEC + INSULIN ASPART****Note** Special Pricing Arrangements apply.**insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges**

11426J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*381.02	31.60	Ryzodeg Penfill [NO]

■ **INSULIN LISPRO + INSULIN LISPRO PROTAMINE****insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges**

8390N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	Humalog Mix25 [LY]

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

8874C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	Humalog Mix50 [LY]

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices**

12234X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	Humalog Mix25 KwikPen [KP]

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices**

12261H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*167.52	31.60	Humalog Mix50 KwikPen [KP]

■ **INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN****insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial**

1426C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*86.57	31.60	Humulin 30/70 [LY]

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL cartridges**

1763T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*141.07	31.60	Humulin 30/70 [LY]

*Insulins and analogues for injection, long-acting*

## ■ INSULIN DETEMIR

**Note** Special Pricing Arrangements apply.

### Restricted benefit

Type 1 diabetes

### insulin detemir 100 units/mL injection, 5 x 3 mL cartridges

9040T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*356.22	31.60	Levemir Penfill [NO]

### insulin detemir 100 units/mL injection, 5 x 3 mL pen devices

12236B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*356.22	31.60	Levemir FlexPen [NF]

## ■ INSULIN GLARGINE

### insulin glargine 100 units/mL injection, 5 x 3 mL cartridges

9039R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*187.42	31.60	Optisulin [GZ]

### insulin glargine 100 units/mL injection, 5 x 3 mL pen devices

11815W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*187.42	31.60	Optisulin SoloStar [WA]

## ■ INSULIN GLARGINE

**Note** Special Pricing Arrangements apply.

### insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices

11308E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*255.97	31.60	Toujeo Solostar [SW]

### insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices

11302W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	5	1	..	*420.87	31.60	Toujeo Solostar [SW]

## BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

### *Biguanides*

## ■ METFORMIN

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### metformin hydrochloride 1 g tablet, 90

8607B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(NP) (MW)</b>	1	5	..	17.76	19.21	<sup>a</sup> APX-METFORMIN [TY]	<sup>a</sup> Blooms The Chemist Metformin 1000 mg [BG]
						<sup>a</sup> Diaformin 1000 [AF]	<sup>a</sup> Diaformin Viatris [MQ]
						<sup>a</sup> Formet 1000 [RW]	<sup>a</sup> Glucobete 1000 [ZS]
						<sup>a</sup> Metformin GH [HQ]	<sup>a</sup> Metformin Sandoz [SZ]
						<sup>a</sup> METFORMIN-WGR [WG]	
			<sup>b</sup> 4.89	22.65	19.21	<sup>a</sup> Diabex 1000 [AL]	

### metformin hydrochloride 1 g modified release tablet, 60

3439B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(NP) (MW)</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Metformin XR 1000 [TX]	<sup>a</sup> Diaformin Alphapharm XR [MQ]
						<sup>a</sup> Diaformin XR 1000 [AF]	<sup>a</sup> METEX XR [RF]
						<sup>a</sup> Metformin Sandoz XR [SZ]	<sup>a</sup> METFORMIN-WGR XR [WG]
						<sup>a</sup> Pharmacor Metformin XR [CR]	
			<sup>b</sup> 5.34	23.10	19.21	<sup>a</sup> Diabex XR 1000 [AL]	

### metformin hydrochloride 500 mg tablet, 100

2430X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(NP) (MW)</b>	1	5	..	16.69	18.14	<sup>a</sup> APX-METFORMIN [TY]	<sup>a</sup> Blooms The Chemist Metformin 500 mg [BG]
						<sup>a</sup> Diaformin [AF]	<sup>a</sup> Diaformin Viatris [MQ]
						<sup>a</sup> FORMET 500 [RF]	<sup>a</sup> Glucobete 500 [ZS]

<sup>a</sup> Metformin GH [HQ] <sup>a</sup> Metformin Sandoz [SZ]  
<sup>a</sup> METFORMIN-WGR [WG]  
<sup>a</sup> Diabex [AL]

**metformin hydrochloride 500 mg modified release tablet, 120**

9435N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Metformin XR 500 [TX] <sup>a</sup> Metex XR [RW] <sup>a</sup> METFORMIN-WGR XR [WG] <sup>a</sup> Diabex XR 500 [AL]	<sup>a</sup> Diaformin Alphapharm XR [MQ] <sup>a</sup> Metformin Sandoz XR [SZ] <sup>a</sup> Pharmacor Metformin XR [CR]
			<sup>B</sup> 5.47	22.16	18.14		

**metformin hydrochloride 850 mg tablet, 60**

1801T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	1	5	..	16.69	18.14	<sup>a</sup> APX-METFORMIN [TY] <sup>a</sup> Diaformin 850 [AF] <sup>a</sup> FORMET 850 [RF] <sup>a</sup> Metformin Sandoz [SZ] <sup>a</sup> Diabex 850 [AL]	<sup>a</sup> Blooms The Chemist Metformin 850 mg [BG] <sup>a</sup> Diaformin Viatris [MQ] <sup>a</sup> Glucobete 850 [ZS] <sup>a</sup> METFORMIN-WGR [WG]
			<sup>B</sup> 5.47	22.16	18.14		

**■ METFORMIN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**metformin hydrochloride 1 g tablet, 90**

14056T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APX-METFORMIN [TY] <sup>a</sup> Diaformin 1000 [AF] <sup>a</sup> Formet 1000 [RW] <sup>a</sup> Metformin GH [HQ] <sup>a</sup> METFORMIN-WGR [WG] <sup>a</sup> Diabex 1000 [AL]	<sup>a</sup> Blooms The Chemist Metformin 1000 mg [BG] <sup>a</sup> Diaformin Viatris [MQ] <sup>a</sup> Glucobete 1000 [ZS] <sup>a</sup> Metformin Sandoz [SZ]
			<sup>B</sup> 9.78	*31.85	23.52		

**metformin hydrochloride 1 g modified release tablet, 60**

13847T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Metformin XR 1000 [TX] <sup>a</sup> Diaformin XR 1000 [AF] <sup>a</sup> Metformin Sandoz XR [SZ] <sup>a</sup> Pharmacor Metformin XR [CR] <sup>a</sup> Diabex XR 1000 [AL]	<sup>a</sup> Diaformin Alphapharm XR [MQ] <sup>a</sup> METEX XR [RF] <sup>a</sup> METFORMIN-WGR XR [WG]
			<sup>B</sup> 10.68	*32.75	23.52		

**metformin hydrochloride 500 mg tablet, 100**

13976N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.93	21.38	<sup>a</sup> APX-METFORMIN [TY] <sup>a</sup> Diaformin [AF] <sup>a</sup> FORMET 500 [RF] <sup>a</sup> Metformin GH [HQ] <sup>a</sup> METFORMIN-WGR [WG] <sup>a</sup> Diabex [AL]	<sup>a</sup> Blooms The Chemist Metformin 500 mg [BG] <sup>a</sup> Diaformin Viatris [MQ] <sup>a</sup> Glucobete 500 [ZS] <sup>a</sup> Metformin Sandoz [SZ]
			<sup>B</sup> 10.94	*30.87	21.38		

**metformin hydrochloride 500 mg modified release tablet, 120**

13899M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Metformin XR 500 [TX] <sup>a</sup> Metex XR [RW] <sup>a</sup> METFORMIN-WGR XR [WG] <sup>a</sup> Diabex XR 500 [AL]	<sup>a</sup> Diaformin Alphapharm XR [MQ] <sup>a</sup> Metformin Sandoz XR [SZ] <sup>a</sup> Pharmacor Metformin XR [CR]
			<sup>B</sup> 10.68	*32.75	23.52		

**metformin hydrochloride 850 mg tablet, 60**

13952H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.93	21.38	<sup>a</sup> APX-METFORMIN [TY] <sup>a</sup> Diaformin 850 [AF] <sup>a</sup> FORMET 850 [RF] <sup>a</sup> Metformin Sandoz [SZ] <sup>a</sup> Diabex 850 [AL]	<sup>a</sup> Blooms The Chemist Metformin 850 mg [BG] <sup>a</sup> Diaformin Viatris [MQ] <sup>a</sup> Glucobete 850 [ZS] <sup>a</sup> METFORMIN-WGR [WG]
			<sup>B</sup> 10.94	*30.87	21.38		

**Sulfonylureas**

## ■ GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glibenclamide 5 mg tablet, 100

2939Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	Daonil [SW]

## ■ GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### glibenclamide 5 mg tablet, 100

13868X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	Daonil [SW]

## ■ GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### gliclazide 30 mg modified release tablet, 100

8535F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.74	20.19	<sup>a</sup> APO-Gliclazide MR [TX] <sup>a</sup> Glyade MR [AF]	<sup>a</sup> Gliclazide MR Viatris [AL] <sup>a</sup> Pharmacor Gliclazide MR [CR]

### gliclazide 60 mg modified release tablet, 60

9302N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.67	19.12	<sup>a</sup> ARDIX GLICLAZIDE 60mg MR [XT] <sup>a</sup> Pharmacor Gliclazide MR [CR]	<sup>a</sup> Gliclazide Lupin MR [GQ]
			<sup>B</sup> 9.95	27.62	19.12	<sup>a</sup> Diamicon 60mg MR [SE]	

### gliclazide 80 mg tablet, 100

2449X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.59	20.04	<sup>a</sup> APX-Gliclazide [TY]	<sup>a</sup> Nidem [RW]

## ■ GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### gliclazide 30 mg modified release tablet, 100

14740T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.03	25.48	<sup>a</sup> APO-Gliclazide MR [TX] <sup>a</sup> Glyade MR [AF]	<sup>a</sup> Gliclazide MR Viatris [AL] <sup>a</sup> Pharmacor Gliclazide MR [CR]

### gliclazide 60 mg modified release tablet, 60

13922R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.89	23.34	<sup>a</sup> ARDIX GLICLAZIDE 60mg MR [XT] <sup>a</sup> Pharmacor Gliclazide MR [CR]	<sup>a</sup> Gliclazide Lupin MR [GQ]
			<sup>B</sup> 19.90	*41.79	23.34	<sup>a</sup> Diamicon 60mg MR [SE]	

### gliclazide 80 mg tablet, 100

13896J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.73	25.18	<sup>a</sup> APX-Gliclazide [TY]	<sup>a</sup> Nidem [RW]

## ■ GLIMEPIRIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glimepiride 1 mg tablet, 30

8450R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

### glimepiride 2 mg tablet, 30

8451T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**glimepiride 3 mg tablet, 30**

8533D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.36	17.81	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**glimepiride 4 mg tablet, 30**

8452W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.90	18.35	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**■ GLIMEPIRIDE**

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glimepiride 1 mg tablet, 30**

13848W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**glimepiride 2 mg tablet, 30**

13870B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**glimepiride 3 mg tablet, 30**

14020X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.27	20.72	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**glimepiride 4 mg tablet, 30**

14055R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.35	21.80	<sup>a</sup> ARX-GLIMEPIRIDE [XT] <sup>a</sup> Glimepiride Sandoz [SZ]	<sup>a</sup> Glimepiride APOTEX [GX] <sup>a</sup> GLIMEPIRIDE-WGR [WG]

**■ GLIPIZIDE**

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glipizide 5 mg tablet, 100**

2440K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.53	22.98	<sup>a</sup> Melizide [AF]	<sup>a</sup> Minidiab [PF]

**■ GLIPIZIDE**

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glipizide 5 mg tablet, 100**

14019W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.61	31.06	<sup>a</sup> Melizide [AF]	<sup>a</sup> Minidiab [PF]

**Combinations of oral blood glucose lowering drugs****■ ALOGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15276**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

10035E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.74	31.60	Nesina Met 12.5/1000 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56**

10033C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	53.38	31.60	Nesina Met 12.5/500 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

10032B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.35	31.60	Nesina Met 12.5/850 [TK]

**■ ALOGLIPTIN + METFORMIN****Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15288**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

13989G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*96.03	31.60	Nesina Met 12.5/1000 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56**

14062D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*93.31	31.60	Nesina Met 12.5/500 [TK]

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

14061C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*95.25	31.60	Nesina Met 12.5/850 [TK]

**■ DAPAGLIFLOZIN + METFORMIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority required (STREAMLINED)****16158**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).  
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority required (STREAMLINED)****15289**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.  
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:  
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),  
(b) Red cell transfusion within the previous 3 months.  
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10510E	1	5	..	54.65	31.60	Xigduo XR 5/1000 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10515K	1	5	..	53.35	31.60	Xigduo XR 10/1000 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10516L	1	5	..	52.57	31.60	Xigduo XR 10/500 [AP]

**■ DAPAGLIFLOZIN + METFORMIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority required (STREAMLINED)****16162**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).  
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority required (STREAMLINED)**



**15267**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

13851B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*95.85	31.60	Xigduo XR 5/1000 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

13875G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*93.25	31.60	Xigduo XR 10/1000 [AP]

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

14028H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*91.69	31.60	Xigduo XR 10/500 [AP]

**■ DAPAGLIFLOZIN + SITAGLIPTIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15269**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**dapagliflozin 10 mg + sitagliptin 100 mg tablet, 28**

14638K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	66.80	31.60	Sidapvia 10/100 [AP]

**■ DAPAGLIFLOZIN + SITAGLIPTIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15270**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**dapagliflozin 10 mg + sitagliptin 100 mg tablet, 28**

14645T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*120.47	31.60	Sidapvia 10/100 [AP]

**■ EMPAGLIFLOZIN + LINAGLIPTIN****Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15269**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

11269D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	77.66	31.60	Glyxambi [BY]

**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

11303X

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	77.66	31.60	Glyxambi [BY]

## ■ EMPAGLIFLOZIN + LINAGLIPTIN

### Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness. Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
GLP-1 - glucagon-like peptide-1 receptor agonist

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**15270**

Diabetes mellitus type 2

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

### empagliflozin 10 mg + linagliptin 5 mg tablet, 30

13904T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*143.29	31.60	Glyxambi [BY]

### empagliflozin 25 mg + linagliptin 5 mg tablet, 30

13958P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*143.29	31.60	Glyxambi [BY]

## ■ EMPAGLIFLOZIN + METFORMIN

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
GLP-1 - glucagon-like peptide-1 receptor agonist

### Authority required (STREAMLINED)

**16158**

Diabetes mellitus type 2

### Clinical criteria:

- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

### Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

### Authority required (STREAMLINED)

**15289**

Diabetes mellitus type 2

### Clinical criteria:

- The condition must be inadequately responsive to metformin.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

10627H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.36	31.60	Jardiamet 5 mg/1000 mg [BY]

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

10633P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.93	31.60	Jardiamet 12.5 mg/500 mg [BY]

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

10677Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.36	31.60	Jardiamet 12.5 mg/1000 mg [BY]

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

10626G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.93	31.60	Jardiamet 5 mg/500 mg [BY]

**■ EMPAGLIFLOZIN + METFORMIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority required (STREAMLINED)****16162**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority required (STREAMLINED)****15267**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13852C NP	2	5	..	*101.27	31.60	Jardiamet 5 mg/1000 mg [BY]

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13903R NP	2	5	..	*98.41	31.60	Jardiamet 12.5 mg/500 mg [BY]

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13987E NP	2	5	..	*101.27	31.60	Jardiamet 12.5 mg/1000 mg [BY]

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14029J NP	2	5	..	*98.41	31.60	Jardiamet 5 mg/500 mg [BY]

**■ LINAGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15276**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10038H NP	1	5	..	56.72	31.60	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10045Q NP	1	5	..	57.55	31.60	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10044P NP	1	5	..	58.03	31.60	Trajentamet [BY]

**■ LINAGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15288**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

13959Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*99.99	31.60	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

14065G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*101.65	31.60	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

13879L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*102.61	31.60	Trajentamet [BY]

**■ SAXAGLIPTIN + DAPAGLIFLOZIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28**

11286B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	76.72	31.60	Qtern 5/10 [AP]

**■ SAXAGLIPTIN + DAPAGLIFLOZIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

### **saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28**

13855F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*141.31	31.60	Qtern 5/10 [AP]

## **■ SAXAGLIPTIN + METFORMIN**

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),  
(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15276**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be inadequately responsive to metformin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### **saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

10055F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	52.75	31.60	Kombiglyze XR 5/500 [AP]

### **saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

10051B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	53.54	31.60	Kombiglyze XR 5/1000 [AP]

### **saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

10048W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	54.76	31.60	Kombiglyze XR 2.5/1000 [AP]

## **■ SAXAGLIPTIN + METFORMIN**

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in

more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15288**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

#### **saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

14030K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*92.05	31.60	Kombiglyze XR 5/500 [AP]

#### **saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

13876H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*93.63	31.60	Kombiglyze XR 5/1000 [AP]

#### **saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

13880M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*96.07	31.60	Kombiglyze XR 2.5/1000 [AP]

### **■ SITAGLIPTIN + METFORMIN**

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15276**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be inadequately responsive to metformin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

#### **sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

10089B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	45.16	31.60	<sup>a</sup> Janumet XR [XW]	<sup>a</sup> Sitagliptin/Metformin Sandoz XR [SZ]



**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

9451K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.37	31.60	<sup>a</sup> Janumet [XW] <sup>a</sup> Sitagliptin/Metformin Mylan 50/1000 [AF] <sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/1000 SUN [RA] <sup>a</sup> Sitagliptin/Metformin Sandoz [SZ] <sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

9449H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.32	31.60	<sup>a</sup> Janumet [XW] <sup>a</sup> Sitagliptin/Metformin Mylan 50/500 [AF] <sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/500 SUN [RA] <sup>a</sup> Sitagliptin/Metformin Sandoz [SZ] <sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

9450J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.05	31.60	<sup>a</sup> Janumet [XW] <sup>a</sup> Sitagliptin/Metformin Mylan 50/850 [AF] <sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/850 SUN [RA] <sup>a</sup> Sitagliptin/Metformin Sandoz [SZ] <sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

10090C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	46.22	31.60	<sup>a</sup> Janumet XR [XW]	<sup>a</sup> Sitagliptin/Metformin Sandoz XR [SZ]

**■ SITAGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15288**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

14031L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*76.87	31.60	<sup>a</sup> Janumet XR [XW]	<sup>a</sup> Sitagliptin/Metformin Sandoz XR [SZ]

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

14035Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*59.29	31.60	<sup>a</sup> Janumet [XW] <sup>a</sup> Sitagliptin/Metformin Mylan 50/1000 [AF] <sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/1000 SUN [RA] <sup>a</sup> Sitagliptin/Metformin Sandoz [SZ] <sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

13994M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*57.19	31.60	<sup>a</sup> Janumet [XW]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/500 SUN [RA]
						<sup>a</sup> Sitagliptin/Metformin Mylan 50/500 [AF]	<sup>a</sup> Sitagliptin/Metformin Sandoz [SZ]
						<sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

14064F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*58.65	31.60	<sup>a</sup> Janumet [XW]	<sup>a</sup> SITAGLIPTIN/METFORMIN 50/850 SUN [RA]
						<sup>a</sup> Sitagliptin/Metformin Mylan 50/850 [AF]	<sup>a</sup> Sitagliptin/Metformin Sandoz [SZ]
						<sup>a</sup> SITAGLO-MET [CR]	<sup>a</sup> Velmetia [XT]

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

13990H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*78.99	31.60	<sup>a</sup> Janumet XR [XW]	<sup>a</sup> Sitagliptin/Metformin Sandoz XR [SZ]

**■ VILDAGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15276**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

5476F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.98	31.60	Galvumet 50/1000 [NV]

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

5474D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	50.67	31.60	Galvumet 50/500 [NV]

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

5475E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.52	31.60	Galvumet 50/850 [NV]

**■ VILDAGLIPTIN + METFORMIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15288**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

#### **vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14032M	2	5	..	*90.51	31.60	Galvumet 50/1000 [NV]

NP

#### **vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13877J	2	5	..	*87.89	31.60	Galvumet 50/500 [NV]

NP

#### **vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13991J	2	5	..	*89.59	31.60	Galvumet 50/850 [NV]

NP

#### *Alpha glucosidase inhibitors*

### ■ ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside, UK) in the case of a shortage.

#### **acarbose 100 mg tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14722W	1	5	..	99.44	31.60	<sup>a</sup> Acarbose 100 mg tablets (Morningside, UK) [DZ]

NP

#### **acarbose 100 mg tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8189B	1	5	..	33.99	31.60	<sup>a</sup> Acarbose Viatris [AL]	<sup>a</sup> GLYBOSAY [RW]

NP

### ■ ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside, UK) in the case of a shortage.

#### **acarbose 50 mg tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14735M	1	5	..	77.94	31.60	<sup>a</sup> Acarbose 50 mg tablets (Morningside, UK) [DZ]

NP

#### **acarbose 50 mg tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8188Y	1	5	..	27.95	29.40	<sup>a</sup> Acarbose Viatris [AL]	<sup>a</sup> GLYBOSAY [RW]

NP

### ■ ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside, UK) in the case of a shortage.

#### **Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **acarbose 100 mg tablet, 90**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13869Y	2	5	..	*54.53	31.60	<sup>a</sup> Acarbose Viatris [AL]	<sup>a</sup> GLYBOSAY [RW]

NP

**acarbose 100 mg tablet, 90**

14734L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*189.01	31.60	<sup>a</sup> Acarbose 100 mg tablets (Morningside, UK) [DZ]

**■ ACARBOSE**

**Note** Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside, UK) in the case of a shortage.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**acarbose 50 mg tablet, 90**

13955L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*42.45	31.60	<sup>a</sup> Acarbose Viatris [AL]	<sup>a</sup> GLYBOSAY [RW]

**acarbose 50 mg tablet, 90**

14726C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*143.87	31.60	<sup>a</sup> Acarbose 50 mg tablets (Morningside, UK) [DZ]

*Thiazolidinediones***■ PIOGLITAZONE****Restricted benefit**

Diabetes mellitus type 2

**pioglitazone 15 mg tablet, 28**

8694N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.10	21.55	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

**pioglitazone 30 mg tablet, 28**

8695P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	23.69	25.14	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

**pioglitazone 45 mg tablet, 28**

8696Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	26.76	28.21	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

**■ PIOGLITAZONE****Restricted benefit**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pioglitazone 15 mg tablet, 28**

13898L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*26.75	28.20	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

**pioglitazone 30 mg tablet, 28**

13921Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*33.93	31.60	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

**pioglitazone 45 mg tablet, 28**

14057W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*40.07	31.60	<sup>a</sup> Actos [EW] <sup>a</sup> ARX-PIOGLITAZONE [XT]	<sup>a</sup> APOTEX-Pioglitazone [TX] <sup>a</sup> Vexazone [AF]

*Dipeptidyl peptidase 4 (DPP-4) inhibitors***■ ALOGLIPTIN**

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15261**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

#### **alogliptin 6.25 mg tablet, 28**

2944Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.95	31.60	Nesina [TK]

#### **alogliptin 12.5 mg tablet, 28**

2933J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.95	31.60	Nesina [TK]

#### **alogliptin 25 mg tablet, 28**

2986E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.95	31.60	Nesina [TK]

### **■ ALOGLIPTIN**

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15287**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

#### **alogliptin 6.25 mg tablet, 28**

13897K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*90.45	31.60	Nesina [TK]

#### **alogliptin 12.5 mg tablet, 28**

13977P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*90.45	31.60	Nesina [TK]

**alogliptin 25 mg tablet, 28**

13953J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*90.45	31.60	Nesina [TK]

**■ LINAGLIPTIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15261**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 5 mg tablet, 30**

3387G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.70	31.60	Trajenta [BY]

**■ LINAGLIPTIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15287**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 5 mg tablet, 30**

13954K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*95.95	31.60	Trajenta [BY]

## ■ SAXAGLIPTIN

### Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
 DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
 GLP-1 - glucagon-like peptide-1 receptor agonist

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**15261**

Diabetes mellitus type 2

### Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### saxagliptin 5 mg tablet, 28

8983T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	51.95	31.60	Onglyza [AP]

### saxagliptin 2.5 mg tablet, 28

10128C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	51.95	31.60	Onglyza [AP]

## ■ SAXAGLIPTIN

### Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
 DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
 GLP-1 - glucagon-like peptide-1 receptor agonist

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**15287**

Diabetes mellitus type 2

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### saxagliptin 5 mg tablet, 28

13923T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*90.45	31.60	Onglyza [AP]

**saxagliptin 2.5 mg tablet, 28**

13895H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*90.45	31.60	Onglyza [AP]	

**■ SITAGLIPTIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15261**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**sitagliptin 100 mg tablet, 28**

9182G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	34.24	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xelevia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**sitagliptin 25 mg tablet, 28**

9180E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	34.24	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xelevia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**sitagliptin 50 mg tablet, 28**

9181F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	34.24	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xelevia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**■ SITAGLIPTIN****Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist



**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15287**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**sitagliptin 100 mg tablet, 28**

13871C

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*55.03	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xeluvia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**sitagliptin 25 mg tablet, 28**

14021Y

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*55.03	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xeluvia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**sitagliptin 50 mg tablet, 28**

14058X

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*55.03	31.60	<sup>a</sup> Januvia [XW] <sup>a</sup> Sitagliptin Mylan [AF] <sup>a</sup> Sitagliptin SUN [RA] <sup>a</sup> Xeluvia [XT]	<sup>a</sup> Sitagliptin Lupin [GQ] <sup>a</sup> Sitagliptin Sandoz Pharma [SZ] <sup>a</sup> Sitaglo [CR]

**■ VILDAGLIPTIN****Note Definition:**

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness. Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note Abbreviations used in the restriction are as follows:**

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****15261**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg tablet, 60**

3415R

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	50.59	31.60	Galvus [NV]

## ■ VILDAGLIPTIN

### Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
 DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
 GLP-1 - glucagon-like peptide-1 receptor agonist

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

15287

Diabetes mellitus type 2

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### vildagliptin 50 mg tablet, 60

13846R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*87.73	31.60	Galvus [NV]

### Glucagon-like peptide-1 (GLP-1) analogues

## ■ DULAGLUTIDE

### Note Special Pricing Arrangements apply.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
 DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
 GLP-1 - glucagon-like peptide-1 receptor agonist

### Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

### Authority required (STREAMLINED)

15263

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

### Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

### dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

14150R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	134.27	31.60	Trulicity [LY]

## ■ DULAGLUTIDE

### Note Special Pricing Arrangements apply.

### Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')  
 DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')  
 GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### **Authority required**

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

#### **Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

#### **dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices**

11364D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	134.27	31.60	Trulicity [LY]

### ■ SEMAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

#### **Authority required (STREAMLINED)**

**15263**

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

#### **semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

14163K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	134.27	31.60	Ozempic [NO]

#### **semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device**

14149Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	134.27	31.60	Ozempic [NO]

### ■ SEMAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### **Authority required**

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

#### **Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**

- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

12075M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	134.27	31.60	Ozempic [NO]

**semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device**

12080T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	134.27	31.60	Ozempic [NO]

**Sodium-glucose co-transporter 2 (SGLT2) inhibitors****■ DAPAGLIFLOZIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****13230**

Chronic kidney disease

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m<sup>2</sup> inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**dapagliflozin 10 mg tablet, 28**

13106T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	52.82	31.60	Forxiga [AP]

**■ DAPAGLIFLOZIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15047**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

12823X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	52.82	31.60	Forxiga [AP]

## ■ DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**15051**

Chronic heart failure

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

### **dapagliflozin 10 mg tablet, 28**

14054Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*92.19	31.60	Forxiga [AP]

## ■ DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**14471**

Chronic heart failure

#### **Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

### **dapagliflozin 10 mg tablet, 28**

14073Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	52.82	31.60	Forxiga [AP]

## ■ DAPAGLIFLOZIN

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

### Authority required (STREAMLINED)

**16220**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au). High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

#### **Authority required (STREAMLINED)**

**15311**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

#### **Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

### **dapagliflozin 10 mg tablet, 28**

10011X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.82	31.60	Forxiga [AP]

NP

## ▪ DAPAGLIFLOZIN

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

#### **Authority required (STREAMLINED)**

**16164**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

#### **Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

#### **Authority required (STREAMLINED)**

**15265**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

#### **Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

#### **Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.  
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 10 mg tablet, 28**

13844P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*92.19	31.60	Forxiga [AP]

**■ EMPAGLIFLOZIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15047**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

12918X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.41	31.60	Jardiance [BY]

**■ EMPAGLIFLOZIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15051**

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

14018T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*97.37	31.60	Jardiance [BY]

**■ EMPAGLIFLOZIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****14471**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

13695T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.41	31.60	Jardiance [BY]

**■ EMPAGLIFLOZIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****13230**

Chronic kidney disease

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m<sup>2</sup> inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**empagliflozin 10 mg tablet, 30**

14092Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.41	31.60	Jardiance [BY]

**■ EMPAGLIFLOZIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority required (STREAMLINED)****16220**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority required (STREAMLINED)**



**15311**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

10206E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	55.41	31.60	Jardiance [BY]

**empagliflozin 25 mg tablet, 30**

10202Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	55.63	31.60	Jardiance [BY]

**■ EMPAGLIFLOZIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority required (STREAMLINED)****16164**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at [www.cvdcheck.org.au](http://www.cvdcheck.org.au).

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority required (STREAMLINED)****15265**

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

- (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
- (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

13845Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*97.37	31.60	Jardiance [BY]

**empagliflozin 25 mg tablet, 30**

13920P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*97.81	31.60	Jardiance [BY]

## ■ VITAMINS

### VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

#### *Vitamin D and analogues*

## ■ CALCITRIOL

### Authority required (STREAMLINED)

**5401**

Hypocalcaemia

#### Clinical criteria:

- The condition must be due to renal disease.

### Authority required (STREAMLINED)

**5255**

Hypoparathyroidism

### Authority required (STREAMLINED)

**5089**

Hypophosphataemic rickets

### Authority required (STREAMLINED)

**5114**

Vitamin D-resistant rickets

### Authority required (STREAMLINED)

**5402**

Established osteoporosis

#### Clinical criteria:

- Patient must have fracture due to minimal trauma.  
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	29.58	31.03	<sup>a</sup> Calciprox [ZS]	<sup>a</sup> CALITROL [XT]
			<sup>b</sup> 2.29	31.87	31.03	<sup>a</sup> Sical [AF]	
						<sup>a</sup> Rocaltrol [IX]	

## ■ CALCITRIOL

### Authority required (STREAMLINED)

**14322**

Hypocalcaemia

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

### Authority required (STREAMLINED)

**14287**

Hypoparathyroidism

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### Authority required (STREAMLINED)

**14231**

Hypophosphataemic rickets

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### Authority required (STREAMLINED)

**14296**

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14259**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
  - Patient must have fracture due to minimal trauma.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

13457G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*45.71	31.60	<sup>a</sup> Calciprox [ZS]	<sup>a</sup> CALITROL [XT]
						<sup>a</sup> Sical [AF]	
			<sup>B</sup> 4.58	*50.29	31.60	<sup>a</sup> Rocaltrol [IX]	

**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12***Vitamin B1, plain***■ THIAMINE****Authority required (STREAMLINED)****5139**

Thiamine deficiency

**Clinical criteria:**

- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

1070H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.35	18.80	Betavit [PP]

**■ THIAMINE****Authority required (STREAMLINED)****14319**

Thiamine deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

13354W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*21.25	22.70	Betavit [PP]

**■ MINERAL SUPPLEMENTS****CALCIUM***Calcium***■ CALCIUM****Authority required (STREAMLINED)****4586**

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

3117C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	24.60	26.05	Calci-Tab 600 [AE]

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

11726E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*29.55	31.00	Cal-500 [PP]

**■ CALCIUM****Authority required (STREAMLINED)****14228**

Hyperphosphataemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

13547B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*35.75	31.60	Calci-Tab 600 [AE]

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

13485R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	1	..	*45.63	31.60	Cal-500 [PP]

**POTASSIUM***Potassium***■ POTASSIUM CHLORIDE****potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

1841X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.29	26.74	Span-K [AS]

**■ POTASSIUM CHLORIDE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

13357B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*37.13	31.60	Span-K [AS]

**■ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE****potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

3012M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	25.82	27.27	Chlorvescent [AS]

**■ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

13486T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*38.19	31.60	Chlorvescent [AS]

**OTHER MINERAL SUPPLEMENTS***Magnesium***■ MAGNESIUM****Authority required (STREAMLINED)****5506**

Hypomagnesaemia

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)****5466**

Chronic renal disease

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**magnesium 37.4 mg tablet, 50**

5146W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	19.19	20.64	MagMin (PBS) [BB]	Mag-Sup [PP]

NP

## OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

#### Amino acids and derivatives

#### ■ BETAINE

**Authority required**

Homocystinuria

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
  - The condition must be treated by or in consultation with a metabolic physician.
- The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

10119N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	522.17	31.60	Cystadane [RJ]

#### Various alimentary tract and metabolism products

#### ■ MIGALASTAT

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Fabry disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m<sup>2</sup>, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; OR
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; OR
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiepileptic medications for peripheral neuropathy; OR
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Population criteria:**

- Patient must be at least 12 years of age.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Fabry disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; OR
- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug, **AND**
- Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m<sup>2</sup> prior to commencing treatment with this drug.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Population criteria:**

- Patient must be at least 12 years of age.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**migalastat 123 mg capsule, 14**

14573B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	28076.45	31.60	Galafold [FT]

**▪ SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11970B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	4043.35	31.60	Kuvan [IO]

▪ **SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

10087X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*4819.47	31.60	Kuvan [IO]

▪ **SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must be untreated with this drug; OR
- Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; OR
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; OR
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11971C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4043.35	31.60	Kuvan [IO]

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

11676M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	832.89	31.60	Kuvan [IO]

**■ SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Authority required**

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11973E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4043.35	31.60	Kuvan [IO]

**■ SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

10086W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*4819.47	31.60	Kuvan [IO]

**■ SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing. Blood phenylalanine levels must be based on measurements taken during stable periods of the condition. Dietary phenylalanine intake must be maintained at a constant level.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing

**Treatment criteria:**

- Must be treated by a metabolic physician; OR



- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

11983Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	4043.35	31.60	Kuvan [IO]

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

11691H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*4819.47	31.60	Kuvan [IO]

**■ SAPROPTERIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Request an appropriate maximum quantity based on testing response to treatment for 7 days, with the number of packs being a whole number, based on dosing no greater than 20 mg/kg per day. Combinations of the sachets and tablets are permitted to reduce high tablet burden.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Clinical criteria:**

- The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU), **AND**
- Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels.

**Treatment criteria:**

- Must be treated by a metabolic physician, **AND**
- Patient must be undergoing treatment with this drug for the first time, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be one of: (i) planning conception, (ii) pregnant.

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

12570N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4043.35	31.60	Kuvan [IO]

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

12579C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	832.89	31.60	Kuvan [IO]

**■ SAPROPTERIN**

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Request an appropriate maximum quantity (with the number of packs being a whole number) to provide approximately 30 days treatment duration per dispensing, based on dosing no greater than 20 mg/kg per day.

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Pre-conception through to when pregnancy first becomes known

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**

- Patient must not be undergoing treatment with this drug under this Treatment phase, following completion of this authority application, for more than 13 cumulative months (assuming 1 month consists of 30 days), **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be actively trying to conceive.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** This PBS listing intends to subsidise up to 13 cumulative months (assuming 1 month consists of 30 days) of treatment during the pre-conception phase per known pregnancy. The time taken to conceive can vary for each patient, but where this treatment phase of 'pre-conception through to when pregnancy becomes first known' exceeds a cumulative 13 months, continued treatment beyond this time up to the point of conception, is not PBS subsidised. 13 cumulative months comprises of the time taken to achieve desired phenylalanine level control and the time taken for pregnancy to become known (e.g. If it takes 3 months to reach desired phenylalanine level control, 10 months of PBS-subsidised treatment remain in which to achieve pregnancy; if it takes only 1 month to reach desired phenylalanine level control, 12 months of PBS-subsidised treatment remain in which to achieve pregnancy)

**Authority required**

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Existing pregnancy to birth

**Population criteria:**

- Patient must be pregnant.

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing further treatment with this drug as a PBS benefit, post-partum in the absence of actively trying to conceive a subsequent child/a known subsequent pregnancy, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Note** Request an appropriate number of repeats (whole number) relative to the expected birth date such that treatment is not continued post-partum by a whole prescription quantity. If the expected birth date is within the next 30 days at the time of the authority application, do not request repeats.

**Note** This PBS listing intends to subsidise treatment only whilst the patient is pregnant. Treatment is to be discontinued upon birth under this listing. Whilst a patient may benefit from continued treatment post-partum, continued treatment with this drug post-partum is not PBS subsidised in the absence of actively trying to conceive again/a known subsequent pregnancy.

**saproterin dihydrochloride 100 mg soluble tablet, 30**

12569M

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	832.89	31.60	Kuvan [IO]

**■ SODIUM PHENYLBUTYRATE****Authority required (STREAMLINED)****9993**

Urea cycle disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone. An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m<sup>2</sup>/day in patients weighing more than 20 kg.

**Authority required (STREAMLINED)****9919**

Urea cycle disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition. An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m<sup>2</sup>/day in patients weighing more than 20 kg.

**sodium phenylbutyrate 483 mg/g granules, 174 g**

11865L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	..	*1561.56	31.60	Pheburane [OH]

**■ TRIENTINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### **Authority required**

Chelation of elevated copper levels

#### **Clinical criteria:**

- Patient must have a diagnosis of Wilson disease, **AND**
- Patient must be intolerant to penicillamine.

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type: (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber; OR
- Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types; OR
- Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types.

Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of: (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels.

Document what these findings were in the patient's medical records. Do not supply them in this authority application.

Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine:

Side effects of penicillamine occurring soon after initiation (within first few weeks/months):

(i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.

Side effects of penicillamine developing later:

(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thrombocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.

At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.

#### **trientine dihydrochloride 250 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13124R	2	5	..	*1797.81	31.60	<sup>a</sup> Trientine Dr. Reddy's [RZ]	<sup>a</sup> Trientine Waymade [IX]

NP

## ■ BLOOD AND BLOOD FORMING ORGANS

## ■ ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

#### *Vitamin K antagonists*

#### ■ WARFARIN

**Caution** The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

#### **warfarin sodium 1 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2843P	1	2	..	18.22	19.67	Coumadin [GO]	Marevan [GT]

NP

#### **warfarin sodium 2 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2209G	1	2	..	18.40	19.85	Coumadin [GO]

NP

#### **warfarin sodium 3 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2844Q	1	2	..	18.46	19.91	Marevan [GT]

NP

#### **warfarin sodium 5 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2211J	1	2	..	18.87	20.32	Coumadin [GO]	Marevan [GT]

NP

#### *Heparin group*

#### ■ ENOXAPARIN SODIUM

##### **Restricted benefit**

Haemodialysis

**enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes**

13688K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	100.11	31.60	<sup>a</sup> Exarane Forte [JU]	<sup>a</sup> Exarane Forte Safety-Lock [JO]

**enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes**

13717Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	122.20	31.60	<sup>a</sup> Exarane Forte [JU]	<sup>a</sup> Exarane Forte Safety-Lock [JO]

**▪ ENOXAPARIN SODIUM****Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes**

13710N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	100.11	31.60	<sup>a</sup> Clexane Forte Safety-Lock [AV] <sup>a</sup> Exarane Forte Safety-Lock [JO]	<sup>a</sup> Exarane Forte [JU]

**enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes**

13729N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	122.20	31.60	<sup>a</sup> Clexane Forte Safety-Lock [AV] <sup>a</sup> Exarane Forte Safety-Lock [JO]	<sup>a</sup> Exarane Forte [JU]

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

8510X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	2	1	..	*76.25	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

8558K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	2	1	..	*69.63	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

8264Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	90.06	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

8262W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	67.79	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

8263X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	71.22	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**▪ ENOXAPARIN SODIUM****Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Restricted benefit**

Haemodialysis

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

8639Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*76.25	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

8716R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*69.63	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

5435C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*169.33	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

8640R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*122.55	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

5434B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*129.75	31.60	<sup>a</sup> Clexane Safety-Lock [AV] <sup>a</sup> Exarane Safety-Lock [JO]	<sup>a</sup> Exarane [JU]

**■ HEPARIN****heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules**

1466E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	44.26	31.60	DBL Heparin Sodium [PF]

*Platelet aggregation inhibitors excl. heparin***■ ASPIRIN****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 100 mg tablet, 112**

8202Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	15.58	17.03	Spren 100 [OW]

**■ CLOPIDOGREL****Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.**clopidogrel 75 mg tablet, 28**

8358X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.55	19.00	<sup>a</sup> Blooms Clopidogrel [BG] <sup>a</sup> Clopidogrel Sandoz Pharma [HX] <sup>a</sup> Iscover [AV] <sup>a</sup> Plavivor 75 [CR]	<sup>a</sup> Clopidogrel Lupin [GQ] <sup>a</sup> Clopidogrel Winthrop [WA] <sup>a</sup> Piax [AF]

**clopidogrel 75 mg tablet, 28**

9354H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.55	19.00	<sup>a</sup> CLOPIDOGREL-WGR [WG] <sup>a</sup> Plidogrel [RF]	<sup>a</sup> Clovix 75 [RW]

**■ CLOPIDOGREL****Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**clopidogrel 75 mg tablet, 28**

13365K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.65	23.10	<sup>a</sup> CLOPIDOGREL-WGR [WG] <sup>a</sup> Plidogrel [RF]	<sup>a</sup> Clovix 75 [RW]

**clopidogrel 75 mg tablet, 28**

13399F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*21.65	23.10	<sup>a</sup> Blooms Clopidogrel [BG]	<sup>a</sup> Clopidogrel Lupin [GQ]

NP

<sup>a</sup> Clopidogrel Sandoz Pharma [HX]  
<sup>a</sup> Iscover [AV]  
<sup>a</sup> Plavacor 75 [CR]

<sup>a</sup> Clopidogrel Winthrop [WA]  
<sup>a</sup> Piax [AF]

## ■ CLOPIDOGREL + ASPIRIN

### clopidogrel 75 mg + aspirin 100 mg tablet, 30

9296G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APX-Clopidogrel/Aspirin 75/100 [TY] <sup>a</sup> DuoPlidogrel [GZ]	<sup>a</sup> DuoCover [AV] <sup>a</sup> Piax Plus Aspirin [AF]

## ■ CLOPIDOGREL + ASPIRIN

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### clopidogrel 75 mg + aspirin 100 mg tablet, 30

13427Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APX-Clopidogrel/Aspirin 75/100 [TY] <sup>a</sup> DuoPlidogrel [GZ]	<sup>a</sup> DuoCover [AV] <sup>a</sup> Piax Plus Aspirin [AF]

## ■ TICAGRELOR

### Authority required (STREAMLINED)

#### 5746

Acute coronary syndrome (myocardial infarction or unstable angina)

#### Clinical criteria:

- The treatment must be in combination with aspirin.

### ticagrelor 90 mg tablet, 56

1418P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	101.19	31.60	<sup>a</sup> ARX-TICAGRELOR [XT] <sup>a</sup> TICALOR [XE]	<sup>a</sup> Brilinta [AP]

## ■ TICAGRELOR

### Authority required (STREAMLINED)

#### 14240

Acute coronary syndrome (myocardial infarction or unstable angina)

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with aspirin.

### ticagrelor 90 mg tablet, 56

13524T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*192.69	31.60	<sup>a</sup> ARX-TICAGRELOR [XT] <sup>a</sup> TICALOR [XE]	<sup>a</sup> Brilinta [AP]

## ■ TIROFIBAN

### Authority required (STREAMLINED)

#### 16123

High risk of unstable angina

#### Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

#### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### Authority required (STREAMLINED)

#### 16147

High risk of unstable angina

#### Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

#### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16063**

Non-Q-wave myocardial infarction

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tirofiban 12.5 mg/50 mL injection, 50 mL vial**

8350L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	183.55	31.60	<sup>a</sup> Aggrastat [AS]	<sup>a</sup> Tirofiban Juno [JU]

**Enzymes****■ TENECTEPLASE**

**Note** Pharmaceutical benefits that have the brand Metalyse 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack and pharmaceutical benefits that have the brand TNKase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack are equivalent for the purposes of substitution in the case of a shortage.

**Restricted benefit**

Acute myocardial infarction

**Clinical criteria:**

- The treatment must be administered within 12 hours of onset of attack.

**tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

13128Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	5162.60	31.60	<sup>a</sup> TNKase (Canada) [QY]	<sup>a</sup> TNKase (Canada) Medsurge Healthcare Pty Ltd [DZ]

**tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack**

8527T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	1971.24	31.60	<sup>a</sup> Metalyse [BY]	

**Direct thrombin inhibitors****■ BIVALIRUDIN****Authority required (STREAMLINED)****4919**

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary intervention.

**bivalirudin 250 mg injection, 1 vial**

8844L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	475.72	31.60	<sup>a</sup> Bivalirudin APOTEX [TX]	<sup>a</sup> BIVALIRUDIN ARX [XT]

**■ DABIGATRAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- age 75 years or older;
- hypertension;
- diabetes mellitus;
- heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 150 mg capsule, 60**

2769R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.88	31.60	<sup>a</sup> ARX-Dabigatran [XT] <sup>a</sup> PHARMACOR DABIGATRAN [CR]	<sup>a</sup> Dabigatran Sandoz [SZ]
			<sup>B</sup> 8.93	57.81	31.60	<sup>a</sup> Pradaxa [BY]	

**dabigatran etexilate 110 mg capsule, 60**

2753X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	49.14	31.60	<sup>a</sup> ARX-Dabigatran [XT] <sup>a</sup> PHARMACOR DABIGATRAN [CR]	<sup>a</sup> Dabigatran Sandoz [SZ]
			<sup>B</sup> 8.93	58.07	31.60	<sup>a</sup> Pradaxa [BY]	

**■ DABIGATRAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4402**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 60**

9320M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	80.10	31.60	<sup>a</sup> ARX-Dabigatran [XT]	<sup>a</sup> Pradaxa [BY]

**dabigatran etexilate 110 mg capsule, 60**

9321N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	49.14	31.60	<sup>a</sup> ARX-Dabigatran [XT] <sup>a</sup> PHARMACOR DABIGATRAN [CR]	<sup>a</sup> Dabigatran Sandoz [SZ]
			<sup>B</sup> 8.93	58.07	31.60	<sup>a</sup> Pradaxa [BY]	

**■ DABIGATRAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14301**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have non-valvular atrial fibrillation, **AND**

- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- age 75 years or older;
- hypertension;
- diabetes mellitus;
- heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 150 mg capsule, 60**

13489Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*84.31	31.60	<sup>a</sup> ARX-Dabigatran [XT] <sup>a</sup> PHARMACOR DABIGATRAN [CR]	<sup>a</sup> Dabigatran Sandoz [SZ]
			<sup>B</sup> 17.86	*102.17	31.60	<sup>a</sup> Pradaxa [BY]	

**dabigatran etexilate 110 mg capsule, 60**

13523R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*84.83	31.60	<sup>a</sup> ARX-Dabigatran [XT] <sup>a</sup> PHARMACOR DABIGATRAN [CR]	<sup>a</sup> Dabigatran Sandoz [SZ]
			<sup>B</sup> 17.86	*102.69	31.60	<sup>a</sup> Pradaxa [BY]	

**■ DABIGATRAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4369**

Prevention of venous thromboembolism

**Treatment criteria:**



- Patient must be undergoing total hip replacement.
- Clinical criteria:**
- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 10**

9318K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*35.69	31.60	Pradaxa [BY]

**dabigatran etexilate 110 mg capsule, 10**

9319L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*25.37	26.82	Pradaxa [BY]

**▪ DABIGATRAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4381**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**dabigatran etexilate 75 mg capsule, 10**

9322P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*35.69	31.60	Pradaxa [BY]

**dabigatran etexilate 110 mg capsule, 10**

9323Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*25.37	26.82	Pradaxa [BY]

***Direct factor Xa inhibitors*****▪ APIXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4402**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 60**

5061J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	69.13	31.60	Eliquis [BQ]

**▪ APIXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4098**

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)****5098**

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 28**

10414D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	38.75	31.60	Eliquis [BQ]

## ■ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4269**

Prevention of stroke or systemic embolism

#### **Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

### Authority required (STREAMLINED)

**4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a history of venous thromboembolism.

### apixaban 2.5 mg tablet, 60

2744K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	69.13	31.60	Eliquis [BQ]

## ■ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4382**

Prevention of venous thromboembolism

#### **Treatment criteria:**

- Patient must be undergoing total knee replacement.

#### **Clinical criteria:**

- Patient must require up to 15 days of therapy.

### Authority required (STREAMLINED)

**4409**

Prevention of venous thromboembolism

#### **Treatment criteria:**

- Patient must be undergoing total hip replacement.

#### **Clinical criteria:**

- Patient must require up to 15 days supply to complete a course of treatment.

### apixaban 2.5 mg tablet, 30

5054B

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	41.30	31.60	Eliquis [BQ]

## ■ APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4381**

Prevention of venous thromboembolism

#### **Treatment criteria:**

- Patient must be undergoing total knee replacement.

#### **Clinical criteria:**

- Patient must require up to 10 days of therapy.

### Authority required (STREAMLINED)

**4359**

Prevention of venous thromboembolism

#### **Treatment criteria:**

- Patient must be undergoing total hip replacement.

#### **Clinical criteria:**

- Patient must require up to 10 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 20**

5500L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	32.02	31.60	Eliquis [BQ]

**■ APIXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14301**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority required (STREAMLINED)****14300**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

13464P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*125.37	31.60	Eliquis [BQ]

**■ APIXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority required (STREAMLINED)****4099**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)****4268**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

2735Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	67.65	31.60	Eliquis [BQ]

**■ APIXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14301**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority required (STREAMLINED)****14264**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)****14318**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

13525W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*122.25	31.60	Eliquis [BQ]

**■ RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**rivaroxaban 10 mg tablet, 30**

11633G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	53.50	31.60	<sup>a</sup> ARX-Rivaroxaban 10 [XT]	<sup>a</sup> iXarola [AL]
						<sup>a</sup> Rivaroxaban Dr.Reddy's [RZ]	<sup>a</sup> Rivaroxaban Lupin [GQ]
						<sup>a</sup> Rivaroxaban Sandoz [SZ]	<sup>a</sup> Rivaroxaban-Teva [TB]
						<sup>a</sup> Rivoxa [CR]	<sup>a</sup> Xarelto [AF]

**■ RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****11013**

Chronic stable atherosclerotic disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy, **AND**
- Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; OR
- Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent, **AND**
- Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; OR
- Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%, **AND**
- The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication, **AND**
- Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

**rivaroxaban 2.5 mg tablet, 60**

12197Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	48.80	31.60	<sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> RIVOXIA [CR]	<sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

■ **RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism


**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

2691P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	48.71	31.60	<sup>a</sup> ARX-Rivaroxaban 15 [XT] <sup>a</sup> Rivaroxaban Dr.Reddy's [RZ] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> iXarola [AL] <sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

■ **RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**4402**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 30**

9467G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	53.50	31.60	<sup>a</sup> ARX-Rivaroxaban 10 [XT] <sup>a</sup> Rivaroxaban Dr.Reddy's [RZ] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> iXarola [AL] <sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

**rivaroxaban 10 mg tablet, 15**

9466F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	33.48	31.60	<sup>a</sup> ARX-Rivaroxaban 10 [XT]	<sup>a</sup> Xarelto [AF]

**■ RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****4382**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 15 days of therapy.

**rivaroxaban 10 mg tablet, 15**

9469J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	33.48	31.60	<sup>a</sup> ARX-Rivaroxaban 10 [XT]	<sup>a</sup> Xarelto [AF]

**■ RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14301**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

13463N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*83.97	31.60	<sup>a</sup> ARX-Rivaroxaban 15 [XT] <sup>a</sup> Rivaroxaban Dr.Reddy's [RZ] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> iXarola [AL] <sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

**■ RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14300**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**rivaroxaban 10 mg tablet, 30**

13521P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*93.55	31.60	<sup>a</sup> ARX-Rivaroxaban 10 [XT]	<sup>a</sup> iXarola [AL]

NP

<sup>a</sup> Rivaroxaban Dr.Reddy's [RZ]    <sup>a</sup> Rivaroxaban Lupin [GQ]  
<sup>a</sup> Rivaroxaban Sandoz [SZ]    <sup>a</sup> Rivaroxaban-Teva [TB]  
<sup>a</sup> Rivoxa [CR]    <sup>a</sup> Xarelto [AF]

## ■ RIVAROXABAN

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**10992**

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

### rivaroxaban 2.5 mg tablet, 60

12192Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.80	31.60	<sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> RIVOXA [CR]	<sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

## ■ RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4098**

Deep vein thrombosis

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

### Authority required (STREAMLINED)

**5098**

Pulmonary embolism

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

### rivaroxaban 15 mg tablet, 42

2160Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	66.33	31.60	<sup>a</sup> ARX-Rivaroxaban 15 [XT] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

## ■ RIVAROXABAN

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**14298**

Chronic stable atherosclerotic disease

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

### rivaroxaban 2.5 mg tablet, 60

13366L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*84.15	31.60	<sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> RIVOXA [CR]	<sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

## ■ RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**4099**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

**4268**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism


**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- age 75 years or older;
- hypertension;
- diabetes mellitus;
- heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

2268J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	48.27	31.60	<sup>a</sup> ARX-Rivaroxaban 20 [XT] <sup>a</sup> Rivaroxaban Dr.Reddy's [RZ] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> iXarola [AL] <sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

▪ **RIVAROXABAN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**14264**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**14300**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

**14318**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**



**14301**

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
  - Patient must have non-valvular atrial fibrillation, **AND**
  - Patient must have one or more risk factors for developing stroke or systemic embolism.
- Risk factors for developing stroke or systemic ischaemic embolism are:
- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  - (ii) age 75 years or older;
  - (iii) hypertension;
  - (iv) diabetes mellitus;
  - (v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

13462M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*83.09	31.60	<sup>a</sup> ARX-Rivaroxaban 20 [XT] <sup>a</sup> Rivaroxaban Dr.Reddy's [RZ] <sup>a</sup> Rivaroxaban Sandoz [SZ] <sup>a</sup> Rivoxa [CR]	<sup>a</sup> iXarola [AL] <sup>a</sup> Rivaroxaban Lupin [GQ] <sup>a</sup> Rivaroxaban-Teva [TB] <sup>a</sup> Xarelto [AF]

*Other antithrombotic agents***■ FONDAPARINUX****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****5781**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED)****5808**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes**

8775W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3.5	..	..	*117.89	31.60	Arixtra [AS]

**■ ANTIHEMORRHAGICS****ANTIFIBRINOLYTICS***Amino acids***■ TRANEXAMIC ACID****tranexamic acid 500 mg tablet, 100**

2180R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	39.09	31.60	<sup>a</sup> APO-Tranexamic Acid [TX]	<sup>a</sup> Tranexamic Acid Lupin [GQ]
			<sup>B</sup> 8.31	47.40	31.60	<sup>a</sup> Cyklokapron [PF]	

**■ ANTIANEMIC PREPARATIONS****IRON PREPARATIONS***Iron bivalent, oral preparations***■ FERROUS FUMARATE****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60**

8985X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	1	..	19.79	21.24	Ferro-tab [AE]

## ■ FERROUS SULFATE

**ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL**

8815Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	23.12	24.57	Ferro-Liquid [AE]

*Iron, parenteral preparations*

## ■ FERRIC CARBOXYMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial**

11702X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	285.60	31.60	Ferinject [CS]

**iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial**

10104T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	1	..	*285.59	31.60	Ferinject [CS]

## ■ FERRIC DERISOMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial**

11615H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*424.17	31.60	Monofer [FK]

**iron (as ferric derisomaltose) 1 g/10 mL injection, 10 mL vial**

12049E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	285.60	31.60	Monofer [FK]

## ■ IRON POLYMALTOSE

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

2593L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	34.96	31.60	Ferrosig [SI]

## ■ IRON POLYMALTOSE

**Authority required (STREAMLINED)**

**4302**

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

2805P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	34.96	31.60	Ferrosig [SI]

## ■ IRON SUCROSE

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

10229J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	39.53	31.60	Venofer [VL]

## ■ IRON SUCROSE

**Authority required (STREAMLINED)**

**4302**

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

8807M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	39.53	31.60	Venofer [VL]

*Iron in combination with folic acid*

## ■ FERROUS FUMARATE + FOLIC ACID

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60**

9011G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	20.76	22.21	Ferro-f-tab [AE]

**VITAMIN B12 AND FOLIC ACID***Vitamin B12 (cyanocobalamin and analogues)***■ HYDROXOCOBALAMIN**

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B<sub>12</sub> deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

2162T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	17.84	19.29	<sup>a</sup> Cobal-B12 [JU]	<sup>a</sup> Vita-B12 [GH]

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

9048F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	17.84	19.29	<sup>a</sup> Hydroxo-B12 [AS]	<sup>a</sup> Neo-B12 [PF]

*Folic acid and derivatives***■ FOLIC ACID****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 500 microgram tablet, 100**

2958Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	2	..	..	*17.67	19.12	<sup>a</sup> Foltabs 500 [PP]	<sup>a</sup> Megafol 0.5 [AF]

**■ FOLIC ACID**

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 5 mg tablet, 100**

1437P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	1	..	*19.75	21.20	Megafol 5 [AF]

## ■ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### BLOOD AND RELATED PRODUCTS

*Blood substitutes and plasma protein fractions*

## ■ HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

9487H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*35.46	31.60	Voluven 6% [PK]

## ■ OTHER HEMATOLOGICAL AGENTS

### OTHER HEMATOLOGICAL AGENTS

*Drugs used in hereditary angioedema*

## ■ ICATIBANT

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at [www.allergy.org.au](http://www.allergy.org.au))

#### Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

#### **Clinical criteria:**

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

#### Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Increased maximum quantities will be limited to 12 injections per authority prescription.

### **icatibant 30 mg/3 mL injection, 3 mL syringe**

1976B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	662.31	31.60	<sup>a</sup> Cipla Icatibant [LR] <sup>a</sup> Icatibant Lupin [GQ]	<sup>a</sup> Fyzant [JU]

## ■ LANADELUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)

#### **Clinical criteria:**

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug, **AND**
- Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

#### **Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

#### **Population criteria:**

- Patient must be aged 12 years or older.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)

**Clinical criteria:**

- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab, **AND**
- The treatment must not be used in combination with a C1-esterase inhibitor concentrate.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Continuing preventative treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate.

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be aged 12 years or older.

Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Ianadelumab 300 mg/2 mL injection, 2 mL syringe**

12790E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	18602.70	31.60	Takhzyro [TK]

## ■ CARDIOVASCULAR SYSTEM

## ■ CARDIAC THERAPY

### CARDIAC GLYCOSIDES

#### *Digitalis glycosides*

## ■ DIGOXIN

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### digoxin 50 microgram/mL oral liquid, 60 mL

3164M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*43.67	31.60	Lanoxin [AS]

### digoxin 250 microgram tablet, 100

1322N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.37	18.82	<sup>a</sup> Sigmoidin [LN]
			<sup>B</sup> 2.41	19.78	18.82	<sup>a</sup> Lanoxin [AS]

### digoxin 62.5 microgram tablet, 200

2605D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.37	18.82	<sup>a</sup> Sigmoidin-PG [LN]
			<sup>B</sup> 2.41	19.78	18.82	<sup>a</sup> Lanoxin-PG [AS]

## ANTIARRHYTHMICS, CLASS I AND III

### *Antiarrhythmics, class Ia*

## ■ DISOPYRAMIDE

**Note** Pharmaceutical benefits that have the form disopyramide 100 mg capsule in a pack size of 84 can be substituted for a pack size of 100 in the case of a shortage.

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### disopyramide 100 mg capsule, 100

2923W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.93	27.38	<sup>a</sup> Rythmodan [PB]

### disopyramide 100 mg capsule, 84

13280Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1.19	5	..	*87.21	31.60	<sup>a</sup> Rythmodan (Canada) [OJ]

### *Antiarrhythmics, class Ib*

## ■ LIDOCAINE

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### lidocaine hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules

2876J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	35.56	31.60	Xylocard 500 [AS]

### *Antiarrhythmics, class Ic*

## ■ FLECAINIDE

**Caution** Flecainide acetate should be avoided in patients with poor cardiac function.

### Restricted benefit

Serious supra-ventricular cardiac arrhythmias

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Serious ventricular cardiac arrhythmias

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**flecainide acetate 100 mg tablet, 60**

1090J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.64	31.60	<sup>a</sup> APO-Flecainide [TX] <sup>a</sup> Flecatab [AF]	<sup>a</sup> Flecainide Sandoz [SZ]
			<sup>B</sup> 6.12	36.76	31.60	<sup>a</sup> Tambocor [IL]	

**flecainide acetate 50 mg tablet, 60**

1088G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.32	28.77	<sup>a</sup> APO-Flecainide [TX] <sup>a</sup> Flecatab [AF]	<sup>a</sup> Flecainide Sandoz [SZ]
			<sup>B</sup> 5.65	32.97	28.77	<sup>a</sup> Tambocor [IL]	

**Antiarrhythmics, class III****■ AMIODARONE****Note** This drug has been reported to cause frequent and potentially serious toxicity.**Note** Regular monitoring of hepatic and thyroid function is recommended.**Restricted benefit**

Severe cardiac arrhythmias

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**amiodarone hydrochloride 100 mg tablet, 30**

2344J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	<sup>a</sup> Aratac 100 [AF]	<sup>a</sup> Cordarone X 100 [SW]

**amiodarone hydrochloride 200 mg tablet, 30**

2343H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.60	20.05	<sup>a</sup> Amdarone [XT] <sup>a</sup> Aratac 200 [AF]	<sup>a</sup> Amiodarone Sandoz [SZ] <sup>a</sup> Cordarone X 200 [SW]

**■ SOTALOL****Restricted benefit**

Severe cardiac arrhythmias

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sotalol hydrochloride 160 mg tablet, 60**

2043M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.37	21.82	<sup>a</sup> APX-Sotalol [TY] <sup>a</sup> Solavert [RF] <sup>a</sup> SOTALOL-WGR [WG]	<sup>a</sup> Cardol [AF] <sup>a</sup> Sotalol Sandoz [SZ]
			<sup>B</sup> 4.99	25.36	21.82	<sup>a</sup> Sotacor [RW]	

**sotalol hydrochloride 80 mg tablet, 60**

8398B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.36	18.81	<sup>a</sup> APX-Sotalol [TY] <sup>a</sup> Solavert [RF] <sup>a</sup> SOTALOL-WGR [WG]	<sup>a</sup> Cardol [AF] <sup>a</sup> Sotalol Sandoz [SZ]
			<sup>B</sup> 4.58	21.94	18.81	<sup>a</sup> Sotacor [RW]	

**CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES****Adrenergic and dopaminergic agents**

## ■ ADRENALINE (EPINEPHRINE)

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

### adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

### adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

## ■ ADRENALINE (EPINEPHRINE)

**Caution** Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at [www.allergy.org.au](http://www.allergy.org.au).)

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

#### Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

#### Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

#### Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

#### Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

#### Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

### adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*160.17	31.60	<sup>a</sup> Adrenaline Jr Viatris [AF] <sup>a</sup> EpiPen Jr. [AL]	<sup>a</sup> Anapen Junior 150 [XT]

### adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*160.17	31.60	<sup>a</sup> Adrenaline Viatris [AF] <sup>a</sup> EpiPen [AL]	<sup>a</sup> Anapen 300 [XT]

### adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device

12655C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*160.17	31.60	Anapen 500 [XT]

## VASODILATORS USED IN CARDIAC DISEASES

### Organic nitrates

## ■ GLYCERYL TRINITRATE

### glyceryl trinitrate 10 mg/24 hours patch, 30

1516T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	34.73	31.60	Transiderm-Nitro 50 [SZ]



**glyceryl trinitrate 5 mg/24 hours patch, 30**

1515R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	29.68	31.13	Transiderm-Nitro 25 [SZ]

**glyceryl trinitrate 5 mg/24 hours patch, 30**

8027L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	29.68	31.13	Minitran 5 [IL]

**glyceryl trinitrate 15 mg/24 hours patch, 30**

8119H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	37.61	31.60	Minitran 15 [IL]

**■ GLYCERYL TRINITRATE**

**Note** The spray should not be inhaled.

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

8171C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	‡1	5	..	26.09	27.54	Nitrolingual Pumpspray [SW]

**■ GLYCERYL TRINITRATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glyceryl trinitrate 10 mg/24 hours patch, 30**

13580R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*56.01	31.60	Transiderm-Nitro 50 [SZ]

**glyceryl trinitrate 5 mg/24 hours patch, 30**

13490B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*45.91	31.60	Transiderm-Nitro 25 [SZ]

**glyceryl trinitrate 5 mg/24 hours patch, 30**

14371J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*45.91	31.60	Minitran 5 [IL]

**glyceryl trinitrate 15 mg/24 hours patch, 30**

14335L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*61.77	31.60	Minitran 15 [IL]

**■ GLYCERYL TRINITRATE**

**Note** The spray should not be inhaled.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

13549D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	‡2	5	..	*38.73	31.60	Nitrolingual Pumpspray [SW]

**■ ISOSORBIDE DINITRATE****isosorbide dinitrate 5 mg sublingual tablet, 100**

2588F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	2	..	*20.99	22.44	Isordil Sublingual [RW]

**■ ISOSORBIDE DINITRATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**isosorbide dinitrate 5 mg sublingual tablet, 100**

13491C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	4	2	..	*28.51	29.96	Isordil Sublingual [RW]

## ■ ISOSORBIDE MONONITRATE

## isosorbide mononitrate 120 mg modified release tablet, 30

8273K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.78	22.23	<sup>a</sup> Monodur 120 mg [IY]
			<sup>B</sup> 3.37	24.15	22.23	<sup>a</sup> Imdur 120 mg [IX]

## isosorbide mononitrate 60 mg modified release tablet, 30

1558B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Isosorbide Mononitrate [TX]	<sup>a</sup> Duride [AF]
						<sup>a</sup> ISOBIDE MR [RF]	<sup>a</sup> ISOSORBIDE MR-WGR [WG]
			<sup>B</sup> 3.38	20.60	18.67	<sup>a</sup> Imdur Durule [IX]	

## ■ ISOSORBIDE MONONITRATE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## isosorbide mononitrate 120 mg modified release tablet, 30

13611J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*28.11	29.56	<sup>a</sup> Monodur 120 mg [IY]
			<sup>B</sup> 6.74	*34.85	29.56	<sup>a</sup> Imdur 120 mg [IX]

## isosorbide mononitrate 60 mg modified release tablet, 30

13461L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> APO-Isosorbide Mononitrate [TX]	<sup>a</sup> Duride [AF]
						<sup>a</sup> ISOBIDE MR [RF]	<sup>a</sup> ISOSORBIDE MR-WGR [WG]
			<sup>B</sup> 6.76	*27.75	22.44	<sup>a</sup> Imdur Durule [IX]	

*Other vasodilators used in cardiac diseases*

## ■ NICORANDIL

## nicorandil 10 mg tablet, 60

8228C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	22.14	23.59	<sup>a</sup> APO-Nicorandil [TX]	<sup>a</sup> Ikotab [AF]

## nicorandil 20 mg tablet, 60

8229D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	25.55	27.00	<sup>a</sup> APO-Nicorandil [TX]	<sup>a</sup> Ikotab [AF]

## ■ NICORANDIL

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## nicorandil 10 mg tablet, 60

13550E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*30.83	31.60	<sup>a</sup> APO-Nicorandil [TX]	<sup>a</sup> Ikotab [AF]

## nicorandil 20 mg tablet, 60

13551F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*37.65	31.60	<sup>a</sup> APO-Nicorandil [TX]	<sup>a</sup> Ikotab [AF]

## ■ PERHEXILINE

**Note** Regular monitoring of drug serum levels is recommended.

Authority required (STREAMLINED)

**16111**

Angina

**Clinical criteria:**

- The condition must not be responding to other therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

## perhexiline maleate 100 mg tablet, 100

1822X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.95	31.60	Pexsig [AS]

## ■ VERICIGUAT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**13561**

Chronic heart failure

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

### vericiguat 10 mg tablet, 28

13192H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	144.38	31.60	Verquvo [BN]

### vericiguat 2.5 mg tablet, 28

13178N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	144.38	31.60	Verquvo [BN]

### vericiguat 5 mg tablet, 28

13189E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	144.38	31.60	Verquvo [BN]

## ■ VERICIGUAT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The date of the decompensation event and date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Chronic heart failure

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist.

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%, **AND**
- The condition must be stabilised following a decompensation event that required at least one of: (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months, **AND**
- Patient must not have clinical signs of fluid overload, **AND**
- Patient must not have received intravenous treatment for fluid overload in the previous 24 hours, **AND**
- Patient must not have a systolic blood pressure less than 100 mmHg, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**vericiguat 10 mg tablet, 28**

13193J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	144.38	31.60	Verquvo [BN]

**vericiguat 2.5 mg tablet, 28**

13181R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	144.38	31.60	Verquvo [BN]

**vericiguat 5 mg tablet, 28**

13186B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	144.38	31.60	Verquvo [BN]

**OTHER CARDIAC PREPARATIONS***Other cardiac preparations***■ IVABRADINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4979**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

10012Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	46.82	31.60	<sup>a</sup> APO-Ivabradine [TX] <sup>a</sup> IVABRADINE-WGR [WG]	<sup>a</sup> Coralan [SE]

**ivabradine 7.5 mg tablet, 56**

2960T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	46.82	31.60	<sup>a</sup> APO-Ivabradine [TX]	<sup>a</sup> Coralan [SE]

**■ MAVACAMTEN**

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**

- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment.

This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**mavacamten 10 mg capsule, 28**

14137C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2323.30	31.60	Camzyos [BQ]

**mavacamten 15 mg capsule, 28**

14139E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2323.30	31.60	Camzyos [BQ]

**■ MAVACAMTEN**

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Initial treatment (covering the first 12 weeks of therapy)

**Clinical criteria:**

- Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy, **AND**
- Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be symptomatic with NYHA classes II or III.

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

- (1) A completed authority prescription form; and
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) the left ventricular wall thickness in millimetres (mm).
- (4) The details of a genotyping test report if the patient had been tested. State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) if a gene has been identified that is associated with HCM;
  - (c) if any first-degree family relative has a confirmed diagnosis of HCM.
- (5) The details of the LVOT gradient report. State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) the measured LVOT gradient;
  - (c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).
- (6) NYHA status.

- (7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.
- (8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:
- (a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;
- (b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;
- (c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.
- All results and reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

#### **Treatment criteria:**

- Must be treated by a cardiologist; OR
  - Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.
- The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.
- For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **mavacamten 2.5 mg capsule, 28**

14135Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2323.30	31.60	Camzyos [BQ]

#### **mavacamten 5 mg capsule, 28**

14117B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2323.30	31.60	Camzyos [BQ]

### **MAVACAMTEN**

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Subsequent continuing treatment - Maintenance treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather arrangements if at least 6 months on optimal dose is achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response after at least 6 months on the optimal dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have had confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had maximal end-diastolic left ventricular wall thickness, prior to commencing non-PBS-subsidised treatment, which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have had confirmed peak left ventricular outflow tract (LVOT) gradient, prior to commencing non-PBS-subsidised treatment, of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of: (a) Valsalva manoeuvre; (b) exercise, **AND**
- Patient must have had left ventricular ejection fraction (LVEF) of no less than 55% prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless contraindication/ intolerance present, prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have been symptomatic with NYHA classes II or III prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response if received the optimal dose of mavacamten treatment for at least 6 months, defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) LVOT gradient; OR
- Patient must be receiving mavacamten treatment but have not reached at least 6 months on optimal dose to demonstrate a response as defined above.

**Treatment criteria:**

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

- (1) A completed authority prescription form; and
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) the left ventricular wall thickness in millimetres (mm).
- (4) The details of a genotyping test report if the patient had been tested. State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) if a gene has been identified that is associated with HCM;
  - (c) if any first-degree family relative has a confirmed diagnosis of HCM.
- (5) The details of the LVOT gradient report. State all the following:
  - (a) the date, unique identifying number/code or provider number of the report;
  - (b) the measured LVOT gradient;
  - (c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).

(6) NYHA status.

(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.

(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:

(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;

(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;

(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.

All results and reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'maintenance treatment' criteria if at least 6 months on optimal dose of mavacamten treatment is achieved. Where a 'Grandfathered' patient has received fewer than 6 months on optimal dose, or is titrating treatment until optimal dose is achieved, they must qualify under the 'first continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### mavacamten 10 mg capsule, 28

14138D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2323.30	31.60	Camzyos [BQ]

#### mavacamten 15 mg capsule, 28

14124J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2323.30	31.60	Camzyos [BQ]

#### mavacamten 2.5 mg capsule, 28

14123H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2323.30	31.60	Camzyos [BQ]

#### mavacamten 5 mg capsule, 28

14113T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2323.30	31.60	Camzyos [BQ]

## ■ ANTIHYPERTENSIVES

### ANTIADRENERGIC AGENTS, CENTRALLY ACTING

#### Methyldopa

## ■ METHYLDOPA

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### Authority required

Hypertension

#### **Population criteria:**

- Patient must be pregnant.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

#### methyldopa 250 mg tablet, 100

1629R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	5	..	22.26	23.71	<sup>a</sup> Hydopa [AF]
			<sup>B</sup> 3.08	25.34	23.71	<sup>a</sup> Aldomet [AS]

#### Imidazoline receptor agonists



## ■ CLONIDINE

**clonidine hydrochloride 100 microgram tablet, 100**

3145M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.79	27.24	<sup>a</sup> APO-Clonidine [TX] <sup>a</sup> Clonidine Lupin [GQ]	<sup>a</sup> Catapres 100 [IX]

**clonidine hydrochloride 150 microgram tablet, 100**

3141H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.96	31.60	Catapres [IX]

## ■ CLONIDINE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**clonidine hydrochloride 100 microgram tablet, 100**

13578P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*38.13	31.60	<sup>a</sup> APO-Clonidine [TX] <sup>a</sup> Clonidine Lupin [GQ]	<sup>a</sup> Catapres 100 [IX]

**clonidine hydrochloride 150 microgram tablet, 100**

13548C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.47	31.60	Catapres [IX]

## ■ MOXONIDINE

Restricted benefit

Hypertension

**Clinical criteria:**

- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

9019Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.00	19.45	<sup>a</sup> APO-Moxonidine [TX] <sup>a</sup> Moxonidine GX [SZ] <sup>a</sup> MOXONIDINE-WGR [WG] <sup>a</sup> Physiotens [GO]	<sup>a</sup> Moxonidine GH [GQ] <sup>a</sup> Moxonidine Viatris [AL] <sup>a</sup> Moxotens [RF]

**moxonidine 400 microgram tablet, 30**

9020R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.19	22.64	<sup>a</sup> APO-Moxonidine [TX] <sup>a</sup> Moxonidine GX [SZ] <sup>a</sup> MOXONIDINE-WGR [WG] <sup>a</sup> Physiotens [GO]	<sup>a</sup> Moxonidine GH [GQ] <sup>a</sup> Moxonidine Viatris [AL] <sup>a</sup> Moxotens [RF]

## ■ MOXONIDINE

Restricted benefit

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

13579Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.55	24.00	<sup>a</sup> APO-Moxonidine [TX] <sup>a</sup> Moxonidine GX [SZ] <sup>a</sup> MOXONIDINE-WGR [WG] <sup>a</sup> Physiotens [GO]	<sup>a</sup> Moxonidine GH [GQ] <sup>a</sup> Moxonidine Viatris [AL] <sup>a</sup> Moxotens [RF]

**moxonidine 400 microgram tablet, 30**

13552G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.93	30.38	<sup>a</sup> APO-Moxonidine [TX] <sup>a</sup> Moxonidine GX [SZ] <sup>a</sup> MOXONIDINE-WGR [WG] <sup>a</sup> Physiotens [GO]	<sup>a</sup> Moxonidine GH [GQ] <sup>a</sup> Moxonidine Viatris [AL] <sup>a</sup> Moxotens [RF]

**ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING***Alpha-adrenoreceptor antagonists*

## ■ PRAZOSIN

## prazosin 1 mg tablet, 100

1479W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.59	19.04	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## prazosin 2 mg tablet, 100

1480X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.34	20.79	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## prazosin 5 mg tablet, 100

1478T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.02	25.47	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## ■ PRAZOSIN

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## prazosin 1 mg tablet, 100

13553H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.73	23.18	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## prazosin 2 mg tablet, 100

13400G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.23	26.68	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## prazosin 5 mg tablet, 100

13367M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.59	31.60	<sup>a</sup> APO-Prazosin [TX]	<sup>a</sup> Minipress [PF]

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

## Pyrimidine derivatives

## ■ MINOXIDIL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe refractory hypertension

**Clinical criteria:**

- The treatment must be initiated by a consultant physician.

## minoxidil 10 mg tablet, 100

2313R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	44.38	31.60	Loniten [PF]

## ■ MINOXIDIL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe refractory hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be initiated by a consultant physician.

## minoxidil 10 mg tablet, 100

14041B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*75.31	31.60	Loniten [PF]

## ■ DIURETICS

## LOW-CEILING DIURETICS, THIAZIDES

## Thiazides, plain

## ■ HYDROCHLOROTHIAZIDE

## hydrochlorothiazide 25 mg tablet, 100

1484D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.61	23.06	Dithiazide [FF]

## ■ HYDROCHLOROTHIAZIDE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## hydrochlorothiazide 25 mg tablet, 100

13409R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*29.77	31.22	Dithiazide [FF]

## LOW-CEILING DIURETICS, EXCL. THIAZIDES

*Sulfonamides, plain*

## ■ CHLORTALIDONE

## chlortalidone 25 mg tablet, 50

1585K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*21.35	22.80	Hygroton 25 [GH]

## ■ CHLORTALIDONE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## chlortalidone 25 mg tablet, 50

13500M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*29.23	30.68	Hygroton 25 [GH]

## ■ INDAPAMIDE

## indapamide hemihydrate 1.5 mg modified release tablet, 90

8532C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.17	21.62	<sup>a</sup> APO-Indapamide SR [TX] <sup>a</sup> Tenaxil SR [RW]	<sup>a</sup> Odaplix SR [AF]
			<sup>B</sup> 7.72	27.89	21.62	<sup>a</sup> Natrilix SR [SE]	

## indapamide hemihydrate 2.5 mg tablet, 90

2436F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.91	19.36	<sup>a</sup> Dapa-Tabs [AF]	<sup>a</sup> Insig [RW]

## ■ INDAPAMIDE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## indapamide hemihydrate 1.5 mg modified release tablet, 90

13475F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	1	..	*26.89	28.34	<sup>a</sup> APO-Indapamide SR [TX] <sup>a</sup> Tenaxil SR [RW]	<sup>a</sup> Odaplix SR [AF]
			<sup>B</sup> 15.44	*42.33	28.34	<sup>a</sup> Natrilix SR [SE]	

## indapamide hemihydrate 2.5 mg tablet, 90

13378D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	1	..	*22.37	23.82	<sup>a</sup> Dapa-Tabs [AF]	<sup>a</sup> Insig [RW]

## HIGH-CEILING DIURETICS

*Sulfonamides, plain*

## ■ FUROSEMIDE

## furosemide 20 mg/2 mL injection, 5 x 2 mL ampoules

2413B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	16.58	18.03	Lasix [SW]

## CARDIOVASCULAR SYSTEM

### furosemide 10 mg/mL oral liquid, 30 mL

2411X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	3	..	41.20	31.60	Lasix [SW]

### furosemide 40 mg tablet, 100

2412Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	16.17	17.62	<sup>a</sup> APO-Frusemide [TX] <sup>a</sup> FUROSEMIDE-WGR [WG] <sup>a</sup> Uremide [AF]	<sup>a</sup> Frusax [ZS] <sup>a</sup> NOUMED FUROSEMIDE [VO]
			<sup>B</sup> 1.04	17.21	17.62	<sup>a</sup> Frusemix [TY]	

### furosemide 500 mg tablet, 50

2415D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	23.27	24.72	Urex-Forte [RW]

## ■ FUROSEMIDE

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### furosemide 10 mg/mL oral liquid, 30 mL

13504R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡2	3	..	*68.95	31.60	Lasix [SW]

### furosemide 40 mg tablet, 100

13472C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*18.89	20.34	<sup>a</sup> APO-Frusemide [TX] <sup>a</sup> FUROSEMIDE-WGR [WG] <sup>a</sup> Uremide [AF]	<sup>a</sup> Frusax [ZS] <sup>a</sup> NOUMED FUROSEMIDE [VO]
			<sup>B</sup> 2.08	*20.97	20.34	<sup>a</sup> Frusemix [TY]	

### furosemide 500 mg tablet, 50

13474E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*33.09	31.60	Urex-Forte [RW]

## ■ FUROSEMIDE

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

### furosemide 20 mg tablet, 50

1810G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*18.85	20.30	<sup>a</sup> Frusemix-M [TY]	<sup>a</sup> UREMIDE 20 [AF]

### furosemide 20 mg tablet, 100

2414C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	18.84	20.29	<sup>a</sup> APO-Frusemide [TX] <sup>a</sup> UREMIDE 20 [AF]	<sup>a</sup> FUROSEMIDE-WGR [WG]
			<sup>B</sup> 1.06	19.90	20.29	<sup>a</sup> Frusemix-M [TY]	

## ■ FUROSEMIDE

**Note** Pharmaceutical benefits that have the form furosemide 20 mg tablet, 50 and pharmaceutical benefits that have the form furosemide 20 mg tablet, 100 are equivalent for the purposes of substitution.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### furosemide 20 mg tablet, 50

13501N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	1	..	*24.23	25.68	<sup>a</sup> Frusemix-M [TY]	<sup>a</sup> UREMIDE 20 [AF]

### furosemide 20 mg tablet, 100

13473D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*24.23	25.68	<sup>a</sup> APO-Frusemide [TX] <sup>a</sup> UREMIDE 20 [AF]	<sup>a</sup> FUROSEMIDE-WGR [WG]
			<sup>B</sup> 2.12	*26.35	25.68	<sup>a</sup> Frusemix-M [TY]	

## ALDOSTERONE ANTAGONISTS AND OTHER POTASSIUM-SPARING AGENTS

### *Aldosterone antagonists*

## ■ EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4937**

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

### eplerenone 25 mg tablet, 30

8879H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	54.09	31.60	<sup>a</sup> APO-Eplerenone [TX] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [UJ]

### eplerenone 50 mg tablet, 30

8880J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	54.09	31.60	<sup>a</sup> APO-Eplerenone [TX] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [UJ]

## ■ EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14266**

Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

### eplerenone 25 mg tablet, 30

13590G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*94.73	31.60	<sup>a</sup> APO-Eplerenone [TX] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [UJ]

### eplerenone 50 mg tablet, 30

13379E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*94.73	31.60	<sup>a</sup> APO-Eplerenone [TX] <sup>a</sup> Inpler [AF]	<sup>a</sup> ESPLER [RW] <sup>a</sup> Inspra [UJ]

## ■ FINERENONE

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**14097**

Chronic kidney disease with Type 2 diabetes

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m<sup>2</sup> or greater, prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug, **AND**

- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug, **AND**
- The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant, **AND**
- Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic, **AND**
- Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.

**finerenone 10 mg tablet, 28**

13335W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	84.51	31.60	Kerendia [BN]

**finerenone 20 mg tablet, 28**

13316W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	84.51	31.60	Kerendia [BN]

**■ SPIRONOLACTONE**

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 100 mg tablet, 100**

2340E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.27	29.72	<sup>a</sup> Spironolactone Viatris 100 [AL]
			<sup>B</sup> 4.50	32.77	29.72	<sup>a</sup> Spiractin 100 [AF]
			<sup>B</sup> 7.50	35.77	29.72	<sup>a</sup> Aldactone [PF]

**spironolactone 25 mg tablet, 100**

2339D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> Spironolactone Viatris 25 [AL]
			<sup>B</sup> 4.65	21.87	18.67	<sup>a</sup> Spiractin 25 [AF]
			<sup>B</sup> 7.65	24.87	18.67	<sup>a</sup> Aldactone [PF]

**■ SPIRONOLACTONE**

**Caution** Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**spironolactone 100 mg tablet, 100**

14042C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*43.09	31.60	<sup>a</sup> Spironolactone Viatris 100 [AL]
			<sup>B</sup> 9.00	*52.09	31.60	<sup>a</sup> Spiractin 100 [AF]
			<sup>B</sup> 15.00	*58.09	31.60	<sup>a</sup> Aldactone [PF]

**spironolactone 25 mg tablet, 100**

13503Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> Spironolactone Viatris 25 [AL]
			<sup>B</sup> 9.30	*30.29	22.44	<sup>a</sup> Spiractin 25 [AF]
			<sup>B</sup> 15.30	*36.29	22.44	<sup>a</sup> Aldactone [PF]

**DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION***Low-ceiling diuretics and potassium-sparing agents***■ AMILORIDE + HYDROCHLOROTHIAZIDE**

**Caution** Serum electrolytes should be checked regularly.

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

1486F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*23.61	25.06	Moduretic [AS]

**■ AMILORIDE + HYDROCHLOROTHIAZIDE**

**Caution** Serum electrolytes should be checked regularly.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

13410T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*33.75	31.60	Moduretic [AS]

**OTHER DIURETICS***Vasopressin antagonists***■ TOLVAPTAN**

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority required**

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 m<sup>2</sup> at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition. Rapidly progressing disease is defined as either of the following:

A decline in eGFR of greater than or equal to 5 mL/min/1.73 m<sup>2</sup> within one year;

OR

An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m<sup>2</sup> per year over a five year period.

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

11602P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

11597J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

11588X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 15 mg tablet, 28**

12460T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	290.00	31.60	Jinarc [OS]

**tolvaptan 30 mg tablet, 28**

12461W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	290.00	31.60	Jinarc [OS]

**■ TOLVAPTAN**

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority required (STREAMLINED)****8288**

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m<sup>2</sup>, **AND**
- Patient must not have had a kidney transplant.

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

11600M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

11593E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

11596H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	571.53	31.60	<sup>a</sup> Jinarc [OS]	<sup>a</sup> Tolvaptan Lupin [GQ]

**tolvaptan 15 mg tablet, 28**

12457P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	290.00	31.60	Jinarc [OS]

**tolvaptan 30 mg tablet, 28**

12462X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	290.00	31.60	Jinarc [OS]

## PERIPHERAL VASODILATORS

### PERIPHERAL VASODILATORS

*Other peripheral vasodilators*

## PHENOXYBENZAMINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Phaeochromocytoma

#### Restricted benefit

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*678.33	31.60	Amdipharm Mercury (Australia) Pty Limited [GH]

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	752.77	31.60	Dibenyline [GH]

## BETA BLOCKING AGENTS

### BETA BLOCKING AGENTS

*Beta blocking agents, non-selective*

## PROPRANOLOL

**propranolol hydrochloride 10 mg tablet, 100**

2565B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.75	18.20	<sup>a</sup> APO-Propranolol [TX]	<sup>a</sup> PROPRANOLOL-WGR [WG]
			<sup>B</sup> 2.99	19.74	18.20	<sup>a</sup> Deralin 10 [AF]	
			<sup>B</sup> 8.48	25.23	18.20	<sup>a</sup> Inderal [IX]	

**propranolol hydrochloride 40 mg tablet, 100**

2566C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.02	18.47	<sup>a</sup> APO-Propranolol [TX]	<sup>a</sup> PROPRANOLOL-WGR [WG]
			<sup>B</sup> 2.99	20.01	18.47	<sup>a</sup> Deralin 40 [AF]	
			<sup>B</sup> 8.48	25.50	18.47	<sup>a</sup> Inderal [IX]	

## PROPRANOLOL

#### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propranolol hydrochloride 10 mg tablet, 100**

13386M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.05	21.50	<sup>a</sup> APO-Propranolol [TX]	<sup>a</sup> PROPRANOLOL-WGR [WG]
			<sup>B</sup> 5.98	*26.03	21.50	<sup>a</sup> Deralin 10 [AF]	
			<sup>B</sup> 16.96	*37.01	21.50	<sup>a</sup> Inderal [IX]	

**propranolol hydrochloride 40 mg tablet, 100**

13542R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.59	22.04	<sup>a</sup> APO-Propranolol [TX]	<sup>a</sup> PROPRANOLOL-WGR [WG]
			<sup>B</sup> 5.98	*26.57	22.04	<sup>a</sup> Deralin 40 [AF]	
			<sup>B</sup> 16.96	*37.55	22.04	<sup>a</sup> Inderal [IX]	



*Beta blocking agents, selective*■ **ATENOLOL****atenolol 50 mg tablet, 30**

1081X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APX-Atenolol [TY] <sup>a</sup> Atenolol Sandoz [SZ] <sup>a</sup> Blooms The Chemist Atenolol [BG] <sup>a</sup> Tensig [RW]	<sup>a</sup> Atenolol GH [GQ] <sup>a</sup> ATENOLOL-WGR [WG] <sup>a</sup> Noten [AF]
			<sup>B</sup> 13.44	29.61	17.62	<sup>a</sup> Tenormin [IX]	

■ **ATENOLOL****Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

2243C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	50.59	31.60	Atenolol-AFT [AE]

■ **ATENOLOL****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atenolol 50 mg tablet, 30**

13540P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APX-Atenolol [TY] <sup>a</sup> Atenolol Sandoz [SZ] <sup>a</sup> Blooms The Chemist Atenolol [BG] <sup>a</sup> Tensig [RW]	<sup>a</sup> Atenolol GH [GQ] <sup>a</sup> ATENOLOL-WGR [WG] <sup>a</sup> Noten [AF]
			<sup>B</sup> 26.88	*45.77	20.34	<sup>a</sup> Tenormin [IX]	

■ **ATENOLOL****Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

13600T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*87.73	31.60	Atenolol-AFT [AE]

■ **BISOPROLOL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**bisoprolol fumarate 10 mg tablet, 28**

8606Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.00	20.45	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 10 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 10 [AF]
			<sup>B</sup> 4.51	23.51	20.45	<sup>a</sup> Bicar [AL]	

**bisoprolol fumarate 2.5 mg tablet, 28**

8604W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 2.5 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 2.5 [AF]

			<sup>B</sup> 5.51	23.27	19.21	<sup>a</sup> Bicor [AL]	
<b>bisoprolol fumarate 5 mg tablet, 28</b>							
8605X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.89	19.34	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 5 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 5 [AF]
			<sup>B</sup> 4.50	22.39	19.34	<sup>a</sup> Bicor [AL]	

## ■ BISOPROLOL

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Moderate to severe heart failure

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### bisoprolol fumarate 10 mg tablet, 28

13444N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.55	26.00	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 10 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 10 [AF]
			<sup>B</sup> 9.02	*33.57	26.00	<sup>a</sup> Bicor [AL]	

### bisoprolol fumarate 2.5 mg tablet, 28

13419G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 2.5 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 2.5 [AF]
			<sup>B</sup> 11.02	*33.09	23.52	<sup>a</sup> Bicor [AL]	

### bisoprolol fumarate 5 mg tablet, 28

13443M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.33	23.78	<sup>a</sup> APO-Bisoprolol [TX] <sup>a</sup> Bisoprolol generichealth [GQ] <sup>a</sup> BISOPROLOL-WGR [WG] <sup>a</sup> NOUMED BISOPROLOL [VO]	<sup>a</sup> Bicard 5 [RW] <sup>a</sup> Bisoprolol Sandoz [SZ] <sup>a</sup> Bispro 5 [AF]
			<sup>B</sup> 9.00	*31.33	23.78	<sup>a</sup> Bicor [AL]	

## ■ METOPROLOL SUCCINATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Moderate to severe heart failure

### Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

8735R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	41.92	31.60	<sup>a</sup> Metrol-XL 190 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 190 [AP]

### METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

8732N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.87	19.32	<sup>a</sup> Metrol-XL 23.75 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF]

### METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

8733P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	31.67	31.60	<sup>a</sup> Metrol-XL 47.5 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 47.5 [AP]

**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

8734Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.22	31.60	<sup>a</sup> Metrol-XL 95 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 95 [AP]

**■ METOPROLOL SUCCINATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

13420H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*70.39	31.60	<sup>a</sup> Metrol-XL 190 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 190 [AP]

**METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30**

13543T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*49.89	31.60	<sup>a</sup> Metrol-XL 47.5 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 47.5 [AP]

**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

13544W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*58.99	31.60	<sup>a</sup> Metrol-XL 95 [RW] <sup>a</sup> Topreloc-XL [CR]	<sup>a</sup> Minax XL [AF] <sup>a</sup> Toprol-XL 95 [AP]

**■ METOPROLOL TARTRATE****METOPROLOL TARTRATE Tablet 100 mg, 60**

1325R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.43	17.88	Mistrom [ZS] <sup>a</sup> APO-Metoprolol [TX] <sup>a</sup> METOPROLOL-WGR [WG] <sup>a</sup> Minax 100 [AF]	<sup>a</sup> Metoprolol Sandoz [SZ] <sup>a</sup> Metrol 100 [RW]
			<sup>B</sup> 13.15	29.58	17.88	<sup>a</sup> Betaloc [AP]	

**METOPROLOL TARTRATE Tablet 50 mg, 100**

1324Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	Mistrom [ZS] <sup>a</sup> APO-Metoprolol [TX] <sup>a</sup> METOPROLOL-WGR [WG] <sup>a</sup> Minax 50 [AF]	<sup>a</sup> Metoprolol Sandoz [SZ] <sup>a</sup> Metrol 50 [RW]
			<sup>B</sup> 13.15	29.32	17.62	<sup>a</sup> Betaloc [AP]	

**■ METOPROLOL TARTRATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**METOPROLOL TARTRATE Tablet 100 mg, 60**

13541Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.41	20.86	Mistrom [ZS] <sup>a</sup> APO-Metoprolol [TX] <sup>a</sup> METOPROLOL-WGR [WG] <sup>a</sup> Minax 100 [AF]	<sup>a</sup> Metoprolol Sandoz [SZ] <sup>a</sup> Metrol 100 [RW]
			<sup>B</sup> 26.30	*45.71	20.86	<sup>a</sup> Betaloc [AP]	

**METOPROLOL TARTRATE Tablet 50 mg, 100**

13598Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	Mistrom [ZS] <sup>a</sup> APO-Metoprolol [TX] <sup>a</sup> METOPROLOL-WGR [WG] <sup>a</sup> Minax 50 [AF]	<sup>a</sup> Metoprolol Sandoz [SZ] <sup>a</sup> Metrol 50 [RW]
			<sup>B</sup> 26.30	*45.19	20.34	<sup>a</sup> Betaloc [AP]	

## ■ NEBIVOLOL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

9316H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.95	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

**nebivolol 10 mg tablet, 28**

9312D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	39.52	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

**nebivolol 5 mg tablet, 28**

9311C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.51	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

## ■ NEBIVOLOL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

13568D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*50.43	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

**nebivolol 10 mg tablet, 28**

13441K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*65.59	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

**nebivolol 5 mg tablet, 28**

13510C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*59.57	31.60	<sup>a</sup> APO-Nebivolol [TX] <sup>a</sup> Nebivolol Lupin [GQ] <sup>a</sup> Nepiten [AF]	<sup>a</sup> Nebilet [FK] <sup>a</sup> Nebivolol Sandoz [SZ]

*Alpha and beta blocking agents*

## ■ CARVEDILOL

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**carvedilol 6.25 mg tablet, 60**

8256M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 6.25 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 6.25 [PB] <sup>a</sup> Volirop 6.25 [ZS]

**carvedilol 12.5 mg tablet, 60**

8257N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 12.5 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 12.5 [PB] <sup>a</sup> Volirop 12.5 [ZS]

**carvedilol 25 mg tablet, 60**

8258P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.61	20.06	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 25 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 25 [PB] <sup>a</sup> Volirop 25 [ZS]

**carvedilol 3.125 mg tablet, 30**

8255L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.20	18.65	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> Vedilol 3.125 [RW]	<sup>a</sup> Carvidol [RF] <sup>a</sup> Volirop 3.125 [ZS]

**■ CARVEDILOL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**carvedilol 6.25 mg tablet, 60**

13417E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 6.25 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 6.25 [PB] <sup>a</sup> Volirop 6.25 [ZS]

**carvedilol 12.5 mg tablet, 60**

13418F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 12.5 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 12.5 [PB] <sup>a</sup> Volirop 12.5 [ZS]

**carvedilol 25 mg tablet, 60**

13387N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.77	25.22	<sup>a</sup> APO-Carvedilol [TX] <sup>a</sup> CARVEDILOL-WGR [WG] <sup>a</sup> Dicarz [AF] <sup>a</sup> Vedilol 25 [RW]	<sup>a</sup> Carvedilol Sandoz [SZ] <sup>a</sup> Carvidol [RF] <sup>a</sup> Dilatrend 25 [PB] <sup>a</sup> Volirop 25 [ZS]

**■ LABETALOL****Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**labetalol hydrochloride 100 mg tablet, 100**

1566K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	1	5	..	31.13	31.60	Presolol 100 [AF]

**LABETALOL****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**labetalol hydrochloride 100 mg tablet, 100**

13887X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*48.81	31.60	Presolol 100 [AF]

**CALCIUM CHANNEL BLOCKERS****SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS***Dihydropyridine derivatives***AMLODIPINE****amlodipine 5 mg tablet, 30**

2751T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> Amlodipine 5 [RW] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> AMLODIPINE-WGR [WG] <sup>a</sup> APX-AMLODIPINE [TW] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> NOUMED AMLODIPINE [VO] <sup>a</sup> Norvasc [AS]	<sup>a</sup> Amlodipine APOTEX [GX] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms Amlodipine [BG] <sup>a</sup> Nordip [AF] <sup>a</sup> Pharmacor Amlodipine [CR]
			<sup>B</sup> 11.17	27.34	17.62		

**amlodipine 10 mg tablet, 30**

2752W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> Amlodipine 10 [RW] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> AMLODIPINE-WGR [WG] <sup>a</sup> APX-AMLODIPINE [TW] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> NOUMED AMLODIPINE [VO] <sup>a</sup> Norvasc [AS]	<sup>a</sup> Amlodipine APOTEX [GX] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms Amlodipine [BG] <sup>a</sup> Nordip [AF] <sup>a</sup> Pharmacor Amlodipine [CR]
			<sup>B</sup> 11.18	27.35	17.62		

**AMLODIPINE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amlodipine 5 mg tablet, 30**

13532F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Amlodipine 5 [RW] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> AMLODIPINE-WGR [WG] <sup>a</sup> APX-AMLODIPINE [TW] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> NOUMED AMLODIPINE [VO] <sup>a</sup> Norvasc [AS]	<sup>a</sup> Amlodipine APOTEX [GX] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms Amlodipine [BG] <sup>a</sup> Nordip [AF] <sup>a</sup> Pharmacor Amlodipine [CR]
			<sup>B</sup> 22.34	*41.23	20.34		

**amlodipine 10 mg tablet, 30**

13562T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Amlodipine 10 [RW] <sup>a</sup> Amlodipine GH [GQ] <sup>a</sup> AMLODIPINE-WGR [WG] <sup>a</sup> APX-AMLODIPINE [TW] <sup>a</sup> Blooms the Chemist Amlodipine [IB] <sup>a</sup> NOUMED AMLODIPINE [VO] <sup>a</sup> Norvasc [AS]	<sup>a</sup> Amlodipine APOTEX [GX] <sup>a</sup> Amlodipine Sandoz [SZ] <sup>a</sup> APO-Amlodipine [TX] <sup>a</sup> Blooms Amlodipine [BG] <sup>a</sup> Nordip [AF] <sup>a</sup> Pharmacor Amlodipine [CR]
			<sup>B</sup> 22.36	*41.25	20.34		

## ■ FELODIPINE

## felodipine 10 mg modified release tablet, 30

2367N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.76	22.21	<sup>a</sup> Felodil XR 10 [RW]	<sup>a</sup> Felodur ER 10 mg [IY]
						<sup>a</sup> Fendex ER [AF]	
			<sup>B</sup> 3.75	24.51	22.21	<sup>a</sup> Plendil ER [IX]	

## felodipine 2.5 mg modified release tablet, 30

2361G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.80	18.25	<sup>a</sup> Felodur ER 2.5 mg [IY]	<sup>a</sup> Fendex ER [AF]
			<sup>B</sup> 3.97	20.77	18.25	<sup>a</sup> Plendil ER [IX]	

## felodipine 5 mg modified release tablet, 30

2366M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.49	18.94	<sup>a</sup> Felodil XR 5 [RW]	<sup>a</sup> Felodur ER 5 mg [IY]
						<sup>a</sup> Fendex ER [AF]	
			<sup>B</sup> 3.88	21.37	18.94	<sup>a</sup> Plendil ER [IX]	

## ■ FELODIPINE

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## felodipine 10 mg modified release tablet, 30

13531E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.07	29.52	<sup>a</sup> Felodil XR 10 [RW]	<sup>a</sup> Felodur ER 10 mg [IY]
						<sup>a</sup> Fendex ER [AF]	
			<sup>B</sup> 7.50	*35.57	29.52	<sup>a</sup> Plendil ER [IX]	

## felodipine 2.5 mg modified release tablet, 30

13377C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.15	21.60	<sup>a</sup> Felodur ER 2.5 mg [IY]	<sup>a</sup> Fendex ER [AF]
			<sup>B</sup> 7.94	*28.09	21.60	<sup>a</sup> Plendil ER [IX]	

## felodipine 5 mg modified release tablet, 30

13561R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.53	22.98	<sup>a</sup> Felodil XR 5 [RW]	<sup>a</sup> Felodur ER 5 mg [IY]
						<sup>a</sup> Fendex ER [AF]	
			<sup>B</sup> 7.76	*29.29	22.98	<sup>a</sup> Plendil ER [IX]	

## ■ LERCANIDIPINE

## lercanidipine hydrochloride 10 mg tablet, 28

8534E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> ARX-LERCANIDIPINE [TX]	<sup>a</sup> Lercan [RW]
						<sup>a</sup> Lercanidipine APOTEX [GX]	<sup>a</sup> LERCANIDIPINE-WGR [WG]
						<sup>a</sup> Zircol 10 [AL]	
			<sup>B</sup> 3.48	19.65	17.62	<sup>a</sup> Zandip [GO]	

## lercanidipine hydrochloride 20 mg tablet, 28

8679T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> ARX-LERCANIDIPINE [TX]	<sup>a</sup> Lercan [RW]
						<sup>a</sup> Lercanidipine APOTEX [GX]	<sup>a</sup> LERCANIDIPINE-WGR [WG]
						<sup>a</sup> Zircol 20 [AL]	
			<sup>B</sup> 3.50	20.72	18.67	<sup>a</sup> Zandip [GO]	

## ■ LERCANIDIPINE

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## lercanidipine hydrochloride 10 mg tablet, 28

13411W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> ARX-LERCANIDIPINE [TX]	<sup>a</sup> Lercan [RW]
						<sup>a</sup> Lercanidipine APOTEX [GX]	<sup>a</sup> LERCANIDIPINE-WGR [WG]
						<sup>a</sup> Zircol 10 [AL]	
			<sup>B</sup> 6.96	*25.85	20.34	<sup>a</sup> Zandip [GO]	

## lercanidipine hydrochloride 20 mg tablet, 28

13412X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> ARX-LERCANIDIPINE [TX]	<sup>a</sup> Lercan [RW]
						<sup>a</sup> Lercanidipine APOTEX [GX]	<sup>a</sup> LERCANIDIPINE-WGR [WG]

<sup>a</sup> Zircol 20 [AL]<sup>B</sup>7.00 \*27.99 22.44 <sup>a</sup> Zandip [GO]

## ■ NIFEDIPINE

## nifedipine 30 mg modified release tablet, 30

1906H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.35	21.80	APO-Nifedipine XR [TX]

## nifedipine 60 mg modified release tablet, 30

1907J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.12	23.57	APO-Nifedipine XR [TX]

## ■ NIFEDIPINE

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## nifedipine 30 mg modified release tablet, 30

13502P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*27.25	28.70	APO-Nifedipine XR [TX]

## nifedipine 60 mg modified release tablet, 30

13376B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*30.79	31.60	APO-Nifedipine XR [TX]

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

*Phenylalkylamine derivatives*

## ■ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

## verapamil hydrochloride 180 mg modified release tablet, 30

2208F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.80	20.25	<sup>a</sup> Cordilox 180 SR [GT]
			<sup>B</sup> 3.54	22.34	20.25	<sup>a</sup> Isoptin 180 SR [GO]

## verapamil hydrochloride 240 mg modified release tablet, 30

1241H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.59	22.04	<sup>a</sup> Cordilox SR [GT]
			<sup>B</sup> 3.50	24.09	22.04	<sup>a</sup> Isoptin SR [GO]

## verapamil hydrochloride 80 mg tablet, 100

1250T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.08	21.53	<sup>a</sup> Anpec 80 [AF]
			<sup>B</sup> 3.10	23.18	21.53	<sup>a</sup> Isoptin [GO]

## ■ VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## verapamil hydrochloride 180 mg modified release tablet, 30

13434C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.15	25.60	<sup>a</sup> Cordilox 180 SR [GT]
			<sup>B</sup> 7.08	*31.23	25.60	<sup>a</sup> Isoptin 180 SR [GO]

## verapamil hydrochloride 240 mg modified release tablet, 30

13408Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*27.73	29.18	<sup>a</sup> Cordilox SR [GT]
			<sup>B</sup> 7.00	*34.73	29.18	<sup>a</sup> Isoptin SR [GO]

## verapamil hydrochloride 80 mg tablet, 100

13530D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*26.71	28.16	<sup>a</sup> Anpec 80 [AF]
			<sup>B</sup> 6.20	*32.91	28.16	<sup>a</sup> Isoptin [GO]

*Benzothiazepine derivatives*

## ■ DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.



**diltiazem hydrochloride 240 mg modified release capsule, 30**

1313D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.30	22.75	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.64	22.94	22.75	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 360 mg modified release capsule, 30**

8480H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.37	26.82	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.90	27.27	26.82	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 60 mg tablet, 90**

1335G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.42	22.87	<sup>a</sup> Vasocardol [AV]	
			<sup>B</sup> 1.90	23.32	22.87	<sup>a</sup> Cardizem [SW]	

**diltiazem hydrochloride 180 mg modified release capsule, 30**

1312C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.26	20.71	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 1.64	20.90	20.71	<sup>a</sup> Cardizem CD [SW]	

**■ DILTIAZEM**

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**diltiazem hydrochloride 240 mg modified release capsule, 30**

14508N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*29.15	30.60	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 3.28	*32.43	30.60	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 360 mg modified release capsule, 30**

14565N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*37.29	31.60	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 3.80	*41.09	31.60	<sup>a</sup> Cardizem CD [SW]	

**diltiazem hydrochloride 60 mg tablet, 90**

14479C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*29.39	30.84	<sup>a</sup> Vasocardol [AV]	
			<sup>B</sup> 3.80	*33.19	30.84	<sup>a</sup> Cardizem [SW]	

**diltiazem hydrochloride 180 mg modified release capsule, 30**

14564M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.07	26.52	<sup>a</sup> Diltiazem Sandoz CD [SZ]	<sup>a</sup> Vasocardol CD [AV]
			<sup>B</sup> 3.28	*28.35	26.52	<sup>a</sup> Cardizem CD [SW]	

**■ AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM****ACE INHIBITORS, PLAIN***ACE inhibitors, plain***■ CAPTOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Patients unable to take a solid dose form of an ACE inhibitor.

**captopril 5 mg/mL oral liquid, 95 mL**

8760C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	109.28	31.60	Capoten [RW]	

**■ ENALAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**enalapril maleate 10 mg tablet, 30**

1368B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.08	18.53	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	
			<sup>B</sup> 10.41	27.49	18.53	<sup>a</sup> Renitec [AF]	

**enalapril maleate 20 mg tablet, 30**

1369C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.38	18.83	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]

NP						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	
	<sup>B</sup> 10.40	27.78	18.83	<sup>a</sup> Renitec 20 [AF]			
enalapril maleate 5 mg tablet, 30							
1370D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	

## ■ ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### **enalapril maleate 10 mg tablet, 30**

13465Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.71	22.16	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	
						<sup>a</sup> Renitec [AF]	
				<sup>B</sup> 20.82	*41.53	22.16	

### **enalapril maleate 20 mg tablet, 30**

13401H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.31	22.76	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	
						<sup>a</sup> Renitec 20 [AF]	
				<sup>B</sup> 20.80	*42.11	22.76	

### **enalapril maleate 5 mg tablet, 30**

13369P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Acetec [AL]	<sup>a</sup> APO-Enalapril [TX]
						<sup>a</sup> Enalapril Sandoz [SZ]	<sup>a</sup> ENALAPRIL-WGR [WG]
						<sup>a</sup> Malean [RW]	

## ■ FOSINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### **fosinopril sodium 10 mg tablet, 30**

1182F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.05	19.50	<sup>a</sup> APO-Fosinopril [TX]	<sup>a</sup> Monace 10 [AF]

### **fosinopril sodium 20 mg tablet, 30**

1183G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.17	21.62	<sup>a</sup> APO-Fosinopril [TX]	<sup>a</sup> Monace 20 [AF]

## ■ LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### **lisinopril 10 mg tablet, 30**

2457H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 10 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 10 [AL]	
						<sup>a</sup> Zestril [IX]	
				<sup>B</sup> 4.84	22.06	18.67	

### **lisinopril 20 mg tablet, 30**

2458J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.54	18.99	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 20 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 20 [AL]	
						<sup>a</sup> Zestril [IX]	
				<sup>B</sup> 4.83	22.37	18.99	

### **lisinopril 5 mg tablet, 30**

2456G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.18	17.63	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 5 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 5 [AL]	
						<sup>a</sup> Zestril [IX]	
				<sup>B</sup> 4.82	21.00	17.63	

## ■ LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### **Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### lisinopril 10 mg tablet, 30

13584Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 10 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 10 [AL]	
			<sup>B</sup> 9.68	*30.67	22.44	<sup>a</sup> Zestril [IX]	

### lisinopril 20 mg tablet, 30

13402J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.63	23.08	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 20 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 20 [AL]	
			<sup>B</sup> 9.66	*31.29	23.08	<sup>a</sup> Zestril [IX]	

### lisinopril 5 mg tablet, 30

13583X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.91	20.36	<sup>a</sup> APO-Lisinopril [TX]	<sup>a</sup> Fibsol 5 [RW]
						<sup>a</sup> Lisinopril Sandoz [SZ]	<sup>a</sup> LISINOPRIL-WGR [WG]
						<sup>a</sup> Zinopril 5 [AL]	
			<sup>B</sup> 9.64	*28.55	20.36	<sup>a</sup> Zestril [IX]	

## ■ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

### perindopril arginine 2.5 mg tablet, 30

9006B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Perindopril Arginine [TX]	<sup>a</sup> APX-Perindopril Arginine [XT]
						<sup>a</sup> Perindopril Arginine Sandoz [SZ]	<sup>a</sup> Perindopril Arginine-WGR [WG]
						<sup>a</sup> PREXUM 2.5 [RX]	
			<sup>B</sup> 9.74	25.91	17.62	<sup>a</sup> Coversyl 2.5mg [SE]	

### perindopril erbumine 2 mg tablet, 30

3050M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Perindopril [TX]	<sup>a</sup> Blooms the Chemist Perindopril [IB]
						<sup>a</sup> Idaprex 2 [SZ]	<sup>a</sup> Indosyl Mono 2 [RW]
						<sup>a</sup> Perindo [AF]	<sup>a</sup> PERINDOPRIL-WGR [WG]
						<sup>a</sup> PERISYL [AL]	

## ■ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

### perindopril arginine 5 mg tablet, 30

9007C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.86	18.31	<sup>a</sup> APO-Perindopril Arginine [TX]	<sup>a</sup> APX-Perindopril Arginine [XT]
						<sup>a</sup> Perindopril Arginine Sandoz [SZ]	<sup>a</sup> Perindopril Arginine-WGR [WG]
						<sup>a</sup> PREXUM 5 [RX]	
			<sup>B</sup> 9.45	26.31	18.31	<sup>a</sup> Coversyl 5mg [SE]	

### perindopril erbumine 4 mg tablet, 30

3051N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.86	18.31	<sup>a</sup> APO-Perindopril [TX]	<sup>a</sup> Blooms the Chemist Perindopril [IB]
						<sup>a</sup> Idaprex 4 [SZ]	<sup>a</sup> Indosyl Mono 4 [RW]
						<sup>a</sup> Perindo [AF]	<sup>a</sup> PERINDOPRIL-WGR [WG]
						<sup>a</sup> PERISYL [AL]	

## ■ PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**perindopril arginine 10 mg tablet, 30**

9008D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Perindopril Arginine [TX] <sup>a</sup> Perindopril Arginine Sandoz [SZ] <sup>a</sup> PREXUM 10 [RX]	<sup>a</sup> APX-Perindopril Arginine [XT] <sup>a</sup> Perindopril Arginine-WGR [WG]
			<sup>B</sup> 9.75	27.51	19.21	<sup>a</sup> Coversyl 10mg [SE]	

**perindopril erbumine 8 mg tablet, 30**

8704D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Perindopril [TX] <sup>a</sup> Idaprex 8 [SZ] <sup>a</sup> Perindo [AF] <sup>a</sup> PERISYL [AL]	<sup>a</sup> Blooms the Chemist Perindopril [IB] <sup>a</sup> Indosyl Mono 8 [RW] <sup>a</sup> PERINDOPRIL-WGR [WG]

**■ PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril arginine 5 mg tablet, 30**

13585B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.27	21.72	<sup>a</sup> APO-Perindopril Arginine [TX] <sup>a</sup> Perindopril Arginine Sandoz [SZ] <sup>a</sup> PREXUM 5 [RX]	<sup>a</sup> APX-Perindopril Arginine [XT] <sup>a</sup> Perindopril Arginine-WGR [WG]
			<sup>B</sup> 18.90	*39.17	21.72	<sup>a</sup> Coversyl 5mg [SE]	

**perindopril erbumine 4 mg tablet, 30**

13371R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.27	21.72	<sup>a</sup> APO-Perindopril [TX] <sup>a</sup> Idaprex 4 [SZ] <sup>a</sup> Perindo [AF] <sup>a</sup> PERISYL [AL]	<sup>a</sup> Blooms the Chemist Perindopril [IB] <sup>a</sup> Indosyl Mono 4 [RW] <sup>a</sup> PERINDOPRIL-WGR [WG]

**■ PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril arginine 10 mg tablet, 30**

13555K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Perindopril Arginine [TX] <sup>a</sup> Perindopril Arginine Sandoz [SZ] <sup>a</sup> PREXUM 10 [RX]	<sup>a</sup> APX-Perindopril Arginine [XT] <sup>a</sup> Perindopril Arginine-WGR [WG]
			<sup>B</sup> 19.50	*41.57	23.52	<sup>a</sup> Coversyl 10mg [SE]	

**perindopril erbumine 8 mg tablet, 30**

13372T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Perindopril [TX] <sup>a</sup> Idaprex 8 [SZ] <sup>a</sup> Perindo [AF] <sup>a</sup> PERISYL [AL]	<sup>a</sup> Blooms the Chemist Perindopril [IB] <sup>a</sup> Indosyl Mono 8 [RW] <sup>a</sup> PERINDOPRIL-WGR [WG]

**■ PERINDOPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### perindopril arginine 2.5 mg tablet, 30

13494F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Perindopril Arginine [TX] <sup>a</sup> Perindopril Arginine Sandoz [SZ] <sup>a</sup> PREXUM 2.5 [RX]	<sup>a</sup> APX-Perindopril Arginine [XT] <sup>a</sup> Perindopril Arginine-WGR [WG]
			<sup>B</sup> 19.48	*38.37	20.34	<sup>a</sup> Coversyl 2.5mg [SE]	

### perindopril erbumine 2 mg tablet, 30

13404L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Perindopril [TX] <sup>a</sup> Idaprex 2 [SZ] <sup>a</sup> Perindo [AF] <sup>a</sup> PERISYL [AL]	<sup>a</sup> Blooms the Chemist Perindopril [IB] <sup>a</sup> Indosyl Mono 2 [RW] <sup>a</sup> PERINDOPRIL-WGR [WG]

## ■ QUINAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### quinapril 10 mg tablet, 30

1969P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.58	19.03	APO-Quinapril [TX]

### quinapril 20 mg tablet, 30

1970Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.45	19.90	APO-Quinapril [TX]

### quinapril 5 mg tablet, 30

1968N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.28	18.73	ACQUIN [RF]

## ■ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

### ramipril 10 mg capsule, 30

8470T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Prilace [RF] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 10 mg [SW]	<sup>a</sup> APX-Ramipril [TY] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Ramipril Winthrop [WA] <sup>a</sup> Tryzan Caps 10 [AF]

### ramipril 10 mg tablet, 30

1316G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> RAMIPRIL TABS-WGR [WG] <sup>a</sup> Tritace [SW]	<sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Ramipril Viatris [AL]

## ■ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

### ramipril 1.25 mg capsule, 30

9120B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Tryzan Caps 1.25 [AF]

### ramipril 1.25 mg tablet, 30

1944H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]	<sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 1.25 mg [SW]

## ■ RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**ramipril 2.5 mg capsule, 30**

9121C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Ramipril [TX]	<sup>a</sup> Tryzan Caps 2.5 [AF]

**ramipril 2.5 mg tablet, 30**

1945J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 2.5 mg [SW]	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**ramipril 5 mg capsule, 30**

9122D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Ramipril [TX]	<sup>a</sup> Tryzan Caps 5 [AF]

**ramipril 5 mg tablet, 30**

1946K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 5 mg [SW]	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 10 mg capsule, 30**

13430W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Prilace [RF] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 10 mg [SW]	<sup>a</sup> APX-Ramipril [TY] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Ramipril Winthrop [WA] <sup>a</sup> Tryzan Caps 10 [AF]

**ramipril 10 mg tablet, 30**

13368N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> RAMIPRIL TABS-WGR [WG] <sup>a</sup> Tritace [SW]	<sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> Ramipril Viatris [AL]

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 2.5 mg capsule, 30**

13405M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-Ramipril [TX]	<sup>a</sup> Tryzan Caps 2.5 [AF]

**ramipril 2.5 mg tablet, 30**

13466R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 2.5 mg [SW]	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 1.25 mg capsule, 30**

13431X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*18.89	20.34	<sup>a</sup> Tryzan Caps 1.25 [AF]	

**ramipril 1.25 mg tablet, 30**

13582W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]	<sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 1.25 mg [SW]

▪ **RAMIPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 5 mg capsule, 30**

13556L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Ramipril [TX]	<sup>a</sup> Tryzan Caps 5 [AF]

**ramipril 5 mg tablet, 30**

13526X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Ramipril [TX] <sup>a</sup> Ramipril Sandoz [SZ] <sup>a</sup> RAMIPRIL-WGR [WG] <sup>a</sup> Tritace 5 mg [SW]	<sup>a</sup> Prilace [RF] <sup>a</sup> Ramipril Viatris [AL] <sup>a</sup> Ramipril Winthrop [WA]

▪ **TRANDOLAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**trandolapril 1 mg capsule, 28**

2792Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 3.50	17.43 20.93	18.88 18.88	<sup>a</sup> Dolapril 1 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 2 mg capsule, 28**

2793B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 3.50	18.24 21.74	19.69 19.69	<sup>a</sup> Dolapril 2 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 4 mg capsule, 28**

8758Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 3.49	22.45 25.94	23.90 23.90	<sup>a</sup> Dolapril 4 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 500 microgram capsule, 28**

2791X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	.. <sup>B</sup> 3.48	16.17 19.65	17.62 17.62	<sup>a</sup> Dolapril 0.5 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

▪ **TRANDOLAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**trandolapril 1 mg capsule, 28**

13429T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	.. <sup>B</sup> 7.00	*21.41 *28.41	22.86 22.86	<sup>a</sup> Dolapril 1 [RW] <sup>a</sup> Gopten [GO]	<sup>a</sup> Tranalpha [AF]

**trandolapril 2 mg capsule, 28**

13403K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*23.03	24.48	<sup>a</sup> Dolapril 2 [RW]	<sup>a</sup> Tranalpha [AF]

			<sup>B</sup> 7.00	*30.03	24.48	<sup>a</sup> Gopten [GO]	
<b>NP</b>	<b>trandolapril 4 mg capsule, 28</b>						
13467T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*31.45	31.60	<sup>a</sup> Dolapril 4 [RW]	<sup>a</sup> Tranalpha [AF]
			<sup>B</sup> 6.98	*38.43	31.60	<sup>a</sup> Gopten [GO]	
	<b>trandolapril 500 microgram capsule, 28</b>						
13554J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Dolapril 0.5 [RW]	<sup>a</sup> Tranalpha [AF]
			<sup>B</sup> 6.96	*25.85	20.34	<sup>a</sup> Gopten [GO]	

## ACE INHIBITORS, COMBINATIONS

### ACE inhibitors and diuretics

#### ■ ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

##### Restricted benefit

Hypertension

##### **Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

##### **enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

8477E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.83	20.28	<sup>a</sup> Enalapril/HCT Sandoz [SZ]
			<sup>B</sup> 6.96	25.79	20.28	<sup>a</sup> Renitec Plus 20/6 [AF]

#### ■ ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

##### Restricted benefit

Hypertension

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

##### **enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

13439H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.21	25.66	<sup>a</sup> Enalapril/HCT Sandoz [SZ]
			<sup>B</sup> 13.92	*38.13	25.66	<sup>a</sup> Renitec Plus 20/6 [AF]

#### ■ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

##### **perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

2190G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> PREXUM Combi LD 2.5/0.625 [RX]
			<sup>B</sup> 7.86	24.03	17.62	<sup>a</sup> Coversyl Plus LD 2.5mg/0.625mg [SE]

#### ■ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

##### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

##### **perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

13413Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> PREXUM Combi LD 2.5/0.625 [RX]
			<sup>B</sup> 15.72	*34.61	20.34	<sup>a</sup> Coversyl Plus LD 2.5mg/0.625mg [SE]

#### ■ PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.



**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

8449Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Perindopril/Indapamide [TX]	<sup>a</sup> GenRx Perindopril/ Indapamide 4/1.25 [GX]
						<sup>a</sup> Idaprex Combi 4/1.25 [SZ]	<sup>a</sup> Indosyl Combi 4/1.25 [RW]
						<sup>a</sup> Perindo Combi 4/1.25 [AF]	<sup>a</sup> PERINDOPRIL/INDAPAMIDE-WGR 4/1.25 [WG]
						<sup>a</sup> PERISYL COMBI 4/1.25 [AL]	

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

2845R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> Prexum Combi 5/1.25 [RX]
			<sup>B</sup> 7.14	24.36	18.67	<sup>a</sup> Coversyl Plus 5mg/1.25mg [SE]

▪ **PERINDOPRIL + INDAPAMIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

13476G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> APO-Perindopril/Indapamide [TX]	<sup>a</sup> GenRx Perindopril/ Indapamide 4/1.25 [GX]
						<sup>a</sup> Idaprex Combi 4/1.25 [SZ]	<sup>a</sup> Indosyl Combi 4/1.25 [RW]
						<sup>a</sup> Perindo Combi 4/1.25 [AF]	<sup>a</sup> PERINDOPRIL/INDAPAMIDE-WGR 4/1.25 [WG]
						<sup>a</sup> PERISYL COMBI 4/1.25 [AL]	

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

13506W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> Prexum Combi 5/1.25 [RX]
			<sup>B</sup> 14.28	*35.27	22.44	<sup>a</sup> Coversyl Plus 5mg/1.25mg [SE]

▪ **QUINAPRIL + HYDROCHLOROTHIAZIDE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8589C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.04	20.49	Accuretic 10/12.5mg [PF]

**quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8590D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.95	21.40	Accuretic 20/12.5mg [PF]

**ACE inhibitors and calcium channel blockers****■ LERCANIDIPINE + ENALAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

9144G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.44	19.89	Zan-Extra 10/10 [GO]

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

9145H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.22	20.67	Zan-Extra 10/20 [GO]

**■ LERCANIDIPINE + ENALAPRIL**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

13507X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*23.43	24.88	Zan-Extra 10/10 [GO]

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

13477H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.99	26.44	Zan-Extra 10/20 [GO]

**■ PERINDOPRIL + AMLODIPINE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

9349C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.42	20.87	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/10 [TX]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 10/10 [XT]
						<sup>a</sup> Perindopril Arginine/Amlodipine-WGR 10/10 [WG]	<sup>a</sup> Reaptan 10/10 [RX]
			<sup>B</sup> 11.85	31.27	20.87	<sup>a</sup> Coveram 10/10 [SE]	

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

9348B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.73	20.18	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/5 [TX]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 10/5 [XT]

						<sup>a</sup> Perindopril Arginine/Amlodipine-WGR 10/5 [WG]	<sup>a</sup> Reaptan 10/5 [RX]
			<sup>B</sup> 11.54	30.27	20.18	<sup>a</sup> Coveram 10/5 [SE]	

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

9347Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.90	19.35	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/10 [TX] <sup>a</sup> Perindopril Arginine/Amlodipine-WGR 5/10 [WG]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 5/10 [XT] <sup>a</sup> Reaptan 5/10 [RX]
			<sup>B</sup> 11.39	29.29	19.35	<sup>a</sup> Coveram 5/10 [SE]	

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

9346X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/5 [TX] <sup>a</sup> Perindopril Arginine/Amlodipine-WGR 5/5 [WG]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 5/5 [XT] <sup>a</sup> Reaptan 5/5 [RX]
			<sup>B</sup> 11.08	28.30	18.67	<sup>a</sup> Coveram 5/5 [SE]	

▪ **PERINDOPRIL + AMLODIPINE**

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

Stable coronary heart disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

13382H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.39	26.84	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/10 [TX] <sup>a</sup> Perindopril Arginine/Amlodipine-WGR 10/10 [WG]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 10/10 [XT] <sup>a</sup> Reaptan 10/10 [RX]
			<sup>B</sup> 23.70	*49.09	26.84	<sup>a</sup> Coveram 10/10 [SE]	

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

13478J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.01	25.46	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 10/5 [TX] <sup>a</sup> Perindopril Arginine/Amlodipine-WGR 10/5 [WG]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 10/5 [XT] <sup>a</sup> Reaptan 10/5 [RX]
			<sup>B</sup> 23.08	*47.09	25.46	<sup>a</sup> Coveram 10/5 [SE]	

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

13381G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.35	23.80	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/10 [TX] <sup>a</sup> Perindopril Arginine/Amlodipine-WGR 5/10 [WG]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 5/10 [XT] <sup>a</sup> Reaptan 5/10 [RX]
			<sup>B</sup> 22.78	*45.13	23.80	<sup>a</sup> Coveram 5/10 [SE]	

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

13508Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> APO-Perindopril Arginine/Amlodipine 5/5 [TX]	<sup>a</sup> APX-Perindopril Arginine/Amlodipine 5/5 [XT]

<sup>a</sup> Perindopril Arginine/Amlodipine-WGR 5/5 [WG]  
<sup>a</sup> Reaptan 5/5 [RX]  
<sup>a</sup> Coveram 5/5 [SE]

<sup>B</sup>22.16    \*43.15    22.44

### ■ RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

#### Restricted benefit

Hypertension

#### **Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

#### ramipril 5 mg + felodipine 5 mg modified release tablet, 30

2629J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.36	20.81	Triasyn 5.0/5.0 [SW]

### ■ RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

#### Restricted benefit

Hypertension

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

#### ramipril 5 mg + felodipine 5 mg modified release tablet, 30

13534H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.27	26.72	Triasyn 5.0/5.0 [SW]

### ■ TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

#### Restricted benefit

Hypertension

#### **Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

#### trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28

9387C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	23.88	25.33	Tarka 2/180 [GO]

#### trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28

2857J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.95	31.40	Tarka 4/240 [GO]

### ■ TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

#### Restricted benefit

Hypertension

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

#### trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28

13594L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*34.31	31.60	Tarka 2/180 [GO]

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

13591H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*46.45	31.60	Tarka 4/240 [GO]

**ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN***Angiotensin II receptor blockers (ARBs), plain***■ CANDESARTAN****candesartan cilexetil 4 mg tablet, 30**

8295N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 13.45	29.62	17.62	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 8 mg tablet, 30**

8296P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 13.45	29.62	17.62	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 16 mg tablet, 30**

8297Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.59	19.04	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 13.47	31.06	19.04	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 32 mg tablet, 30**

8889W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 11.61	29.37	19.21	<sup>a</sup> Atacand [LM]	

**■ CANDESARTAN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**candesartan cilexetil 4 mg tablet, 30**

13592J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 26.90	*45.79	20.34	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 8 mg tablet, 30**

13436E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 26.90	*45.79	20.34	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 16 mg tablet, 30**

13565Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.73	23.18	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 26.94	*48.67	23.18	<sup>a</sup> Atacand [LM]	

**candesartan cilexetil 32 mg tablet, 30**

13438G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> Adesan [AF] <sup>a</sup> BTC Candesartan [BG] <sup>a</sup> Candesartan Sandoz [SZ]	<sup>a</sup> APO-Candesartan [TX] <sup>a</sup> CANDESAN [RF] <sup>a</sup> CANDESARTAN-WGR [WG]
			<sup>B</sup> 23.22	*45.29	23.52	<sup>a</sup> Atacand [LM]	

## ■ EPROSARTAN

## eprosartan 600 mg tablet, 28

8447N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>T</sup> 2.62	27.74	26.57	Teveten [GO]

## ■ EPROSARTAN

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## eprosartan 600 mg tablet, 28

13912F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	<sup>T</sup> 5.24	*42.03	31.60	Teveten [GO]

## ■ EPROSARTAN

Authority required

Adverse effects occurring with all of the base-priced drugs

Authority required

Drug interactions occurring with all of the base-priced drugs

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

## eprosartan 600 mg tablet, 28

5491B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.74	29.19	Teveten [GO]

## ■ EPROSARTAN

Authority required

Adverse effects occurring with all of the base-priced drugs

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required

Drug interactions occurring with all of the base-priced drugs

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## eprosartan 600 mg tablet, 28

13861M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*42.03	31.60	Teveten [GO]

## ■ IRBESARTAN

## irbesartan 150 mg tablet, 30

8247C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Abisart 150 [AL] <sup>a</sup> AVSARTAN [RF] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Noumed Irbesartan [VO]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG] <sup>a</sup> IRBESARTAN-WGR [WG]
			<sup>B</sup> 3.50	19.67	17.62	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

## irbesartan 300 mg tablet, 30

8248D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> Abisart 300 [AL] <sup>a</sup> AVSARTAN [RF]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG]

<sup>a</sup> Blooms the Chemist Irbesartan [IB]  
<sup>a</sup> IRBESARTAN-WGR [WG]  
<sup>a</sup> Avapro [AV]  
<sup>a</sup> Irbesartan Sandoz [SZ]  
<sup>a</sup> Noumed Irbesartan [VO]  
<sup>a</sup> Karvea [SW]

**irbesartan 75 mg tablet, 30**

8246B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> Abisart 75 [AL] <sup>a</sup> AVSARTAN [RF] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Noumed Irbesartan [VO]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG] <sup>a</sup> IRBESARTAN-WGR [WG]

**IRBESARTAN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**irbesartan 150 mg tablet, 30**

13380F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Abisart 150 [AL] <sup>a</sup> AVSARTAN [RF] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Noumed Irbesartan [VO]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG] <sup>a</sup> IRBESARTAN-WGR [WG]
			<sup>B</sup> 7.00	*25.89	20.34	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

**irbesartan 300 mg tablet, 30**

13564X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> Abisart 300 [AL] <sup>a</sup> AVSARTAN [RF] <sup>a</sup> Blooms the Chemist Irbesartan [IB] <sup>a</sup> IRBESARTAN-WGR [WG]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Noumed Irbesartan [VO]
			<sup>B</sup> 7.00	*27.99	22.44	<sup>a</sup> Avapro [AV]	<sup>a</sup> Karvea [SW]

**irbesartan 75 mg tablet, 30**

13435D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Abisart 75 [AL] <sup>a</sup> AVSARTAN [RF] <sup>a</sup> Irbesartan Sandoz [SZ] <sup>a</sup> Noumed Irbesartan [VO]	<sup>a</sup> APO-Irbesartan [TX] <sup>a</sup> Blooms Irbesartan [BG] <sup>a</sup> IRBESARTAN-WGR [WG]

**OLMESARTAN****olmesartan medoxomil 20 mg tablet, 30**

2147B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.58	19.03	<sup>a</sup> APO-Olmesartan [TX] <sup>a</sup> Blooms The Chemist Olmesartan [BG] <sup>a</sup> Olmesartan - MYL [AF] <sup>a</sup> OLMESARTAN-WGR [WG] <sup>a</sup> Pharmacor Olmesartan 20 [CR]	<sup>a</sup> APX-Olmesartan [TY] <sup>a</sup> OLMERTAN [RW] <sup>a</sup> Olmesartan Sandoz [SZ] <sup>a</sup> Olsetan [MQ]
			<sup>B</sup> 4.00	21.58	19.03	<sup>a</sup> Olmetec [AL]	

**olmesartan medoxomil 40 mg tablet, 30**

2148C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.56	21.01	<sup>a</sup> APO-Olmesartan [TX] <sup>a</sup> Blooms The Chemist Olmesartan [BG] <sup>a</sup> Olmesartan - MYL [AF] <sup>a</sup> OLMESARTAN-WGR [WG] <sup>a</sup> Pharmacor Olmesartan 40 [CR]	<sup>a</sup> APX-Olmesartan [TY] <sup>a</sup> OLMERTAN [RW] <sup>a</sup> Olmesartan Sandoz [SZ] <sup>a</sup> Olsetan [MQ]
			<sup>B</sup> 4.00	23.56	21.01	<sup>a</sup> Olmetec [AL]	

**OLMESARTAN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**olmesartan medoxomil 20 mg tablet, 30**

13505T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*21.71	23.16	<sup>a</sup> APO-Olmesartan [TX]	<sup>a</sup> APX-Olmesartan [TY]

NP							<sup>a</sup> Blooms The Chemist Olmesartan [BG]	<sup>a</sup> OLMERTAN [RW]
							<sup>a</sup> Olmesartan - MYL [AF]	<sup>a</sup> Olmesartan Sandoz [SZ]
							<sup>a</sup> OLMESARTAN-WGR [WG]	<sup>a</sup> Olsetan [MQ]
							<sup>a</sup> Pharmacor Olmesartan 20 [CR]	
							<sup>a</sup> Olmetec [AL]	
			<sup>B</sup> 8.00	*29.71	23.16			

**olmesartan medoxomil 40 mg tablet, 30**

13533G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.67	27.12	<sup>a</sup> APO-Olmesartan [TX]	<sup>a</sup> APX-Olmesartan [TY]
						<sup>a</sup> Blooms The Chemist Olmesartan [BG]	<sup>a</sup> OLMERTAN [RW]
						<sup>a</sup> Olmesartan - MYL [AF]	<sup>a</sup> Olmesartan Sandoz [SZ]
						<sup>a</sup> OLMESARTAN-WGR [WG]	<sup>a</sup> Olsetan [MQ]
						<sup>a</sup> Pharmacor Olmesartan 40 [CR]	
			<sup>B</sup> 8.00	*33.67	27.12	<sup>a</sup> Olmetec [AL]	

**■ TELMISARTAN****telmisartan 40 mg tablet, 28**

8355R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Telmisartan [TX]	<sup>a</sup> Mizart [AF]
						<sup>a</sup> Pharmacor Telmisartan 40 [CR]	<sup>a</sup> Telmisartan Sandoz [SZ]
						<sup>a</sup> TELMISARTAN-WGR [WG]	<sup>a</sup> Teltartan [RW]
						<sup>a</sup> Micardis [BY]	
			<sup>B</sup> 10.00	26.17	17.62		

**telmisartan 80 mg tablet, 28**

8356T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Telmisartan [TX]	<sup>a</sup> Mizart [AF]
						<sup>a</sup> Pharmacor Telmisartan 80 [CR]	<sup>a</sup> Telmisartan Sandoz [SZ]
						<sup>a</sup> TELMISARTAN-WGR [WG]	<sup>a</sup> Teltartan [RW]
						<sup>a</sup> Micardis [BY]	
			<sup>B</sup> 10.00	27.76	19.21		

**■ TELMISARTAN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**telmisartan 40 mg tablet, 28**

13437F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Telmisartan [TX]	<sup>a</sup> Mizart [AF]
						<sup>a</sup> Pharmacor Telmisartan 40 [CR]	<sup>a</sup> Telmisartan Sandoz [SZ]
						<sup>a</sup> TELMISARTAN-WGR [WG]	<sup>a</sup> Teltartan [RW]
						<sup>a</sup> Micardis [BY]	
			<sup>B</sup> 20.00	*38.89	20.34		

**telmisartan 80 mg tablet, 28**

13593K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Telmisartan [TX]	<sup>a</sup> Mizart [AF]
						<sup>a</sup> Pharmacor Telmisartan 80 [CR]	<sup>a</sup> Telmisartan Sandoz [SZ]
						<sup>a</sup> TELMISARTAN-WGR [WG]	<sup>a</sup> Teltartan [RW]
						<sup>a</sup> Micardis [BY]	
			<sup>B</sup> 20.00	*42.07	23.52		

**■ VALSARTAN****valsartan 160 mg tablet, 28**

9370E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.33	21.78	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

**valsartan 40 mg tablet, 28**

9368C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.43	19.88	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

**valsartan 80 mg tablet, 28**

9369D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.81	20.26	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]



## ■ VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

## valsartan 320 mg tablet, 28

9371F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.27	23.72	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

## ■ VALSARTAN

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## valsartan 160 mg tablet, 28

13566B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*27.21	28.66	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

## valsartan 80 mg tablet, 28

13414B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.17	25.62	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

## ■ VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## valsartan 320 mg tablet, 28

13383J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.09	31.60	<sup>a</sup> Dilart [AF]	<sup>a</sup> Diovan [NV]

## ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

*Angiotensin II receptor blockers (ARBs) and diuretics*

## ■ CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

## candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

8504N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Adesan HCT 16/12.5 [AF]	<sup>a</sup> APO-Candesartan HCTZ 16/12.5 [TX]
						<sup>a</sup> Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]	<sup>a</sup> BTC Candesartan HCT [BG]
						<sup>a</sup> CANDESAN COMBI 16/12.5 [RF]	<sup>a</sup> Candesartan/HCT Sandoz [SZ]
						<sup>a</sup> CANDESARTAN HCTZ-WGR 16/12.5 [WG]	<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]
			<sup>B</sup> 13.09	30.85	19.21	<sup>a</sup> Atacand Plus 16/12.5 [LM]	

## candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> Adesan HCT 32/12.5 [AF]	<sup>a</sup> APO-Candesartan HCTZ 32/12.5 [TX]
						<sup>a</sup> BTC Candesartan HCT [BG]	<sup>a</sup> CANDESAN COMBI 32/12.5 [RF]
						<sup>a</sup> Candesartan/HCT Sandoz [SZ]	<sup>a</sup> CANDESARTAN HCTZ-WGR 32/12.5 [WG]
						<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]	
			<sup>B</sup> 11.18	28.94	19.21	<sup>a</sup> Atacand Plus 32/12.5 [LM]	

## candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

9315G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.30	19.75	<sup>a</sup> Adesan HCT 32/25 [AF]	<sup>a</sup> APO-Candesartan HCTZ 32/25 [TX]

<sup>a</sup> BTC Candesartan HCT [BG]	<sup>a</sup> CANDESAN COMBI 32/25 [RF]
<sup>a</sup> Candesartan/HCT Sandoz [SZ]	<sup>a</sup> CANDESARTAN HCTZ-WGR 32/25 [WG]
<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]	
<sup>a</sup> Atacand Plus 32/25 [LM]	

<sup>B</sup>10.85 29.15 19.75

## ■ CANDESARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

13391T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> Adesan HCT 16/12.5 [AF]	<sup>a</sup> APO-Candesartan HCTZ 16/12.5 [TX]
						<sup>a</sup> Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]	<sup>a</sup> BTC Candesartan HCT [BG]
						<sup>a</sup> CANDESAN COMBI 16/12.5 [RF]	<sup>a</sup> Candesartan/HCT Sandoz [SZ]
						<sup>a</sup> CANDESARTAN HCTZ-WGR 16/12.5 [WG]	<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]
						<sup>a</sup> Atacand Plus 16/12.5 [LM]	
				<sup>B</sup> 26.18	*48.25	23.52	

### candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

13452B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> Adesan HCT 32/12.5 [AF]	<sup>a</sup> APO-Candesartan HCTZ 32/12.5 [TX]
						<sup>a</sup> BTC Candesartan HCT [BG]	<sup>a</sup> CANDESAN COMBI 32/12.5 [RF]
						<sup>a</sup> Candesartan/HCT Sandoz [SZ]	<sup>a</sup> CANDESARTAN HCTZ-WGR 32/12.5 [WG]
						<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]	
						<sup>a</sup> Atacand Plus 32/12.5 [LM]	
				<sup>B</sup> 22.36	*44.43	23.52	

### candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

13392W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*23.15	24.60	<sup>a</sup> Adesan HCT 32/25 [AF]	<sup>a</sup> APO-Candesartan HCTZ 32/25 [TX]
						<sup>a</sup> BTC Candesartan HCT [BG]	<sup>a</sup> CANDESAN COMBI 32/25 [RF]
						<sup>a</sup> Candesartan/HCT Sandoz [SZ]	<sup>a</sup> CANDESARTAN HCTZ-WGR 32/25 [WG]
						<sup>a</sup> NOUMED CANDESARTAN/HCT [VO]	
						<sup>a</sup> Atacand Plus 32/25 [LM]	
				<sup>B</sup> 21.70	*44.85	24.60	

## ■ EPROSARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

8624X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	26.25	27.70	Teveten Plus 600/12.5 [GO]

## ■ EPROSARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

14337N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*39.05	31.60	Teveten Plus 600/12.5 [GO]

**■ IRBESARTAN + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8404H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> Abisart HCTZ 150/12.5 [AL] <sup>a</sup> AVSARTAN HCT 150/12.5 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 150/12.5 [WG]
			<sup>B</sup> 3.50	19.67	17.62	<sup>a</sup> Avapro HCT 150/12.5 [AV]	<sup>a</sup> Karvezide 150/12.5 [SW]

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

8405J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.33	18.78	<sup>a</sup> Abisart HCTZ 300/12.5 [AL] <sup>a</sup> AVSARTAN HCT 300/12.5 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 300/12.5 [WG]
			<sup>B</sup> 3.50	20.83	18.78	<sup>a</sup> Avapro HCT 300/12.5 [AV]	<sup>a</sup> Karvezide 300/12.5 [SW]

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

2136K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.67	19.12	<sup>a</sup> Abisart HCTZ 300/25 [AL] <sup>a</sup> AVSARTAN HCT 300/25 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/25 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 300/25 [WG]
			<sup>B</sup> 3.50	21.17	19.12	<sup>a</sup> Avapro HCT 300/25 [AV]	<sup>a</sup> Karvezide 300/25 [SW]

**■ IRBESARTAN + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13572H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Abisart HCTZ 150/12.5 [AL] <sup>a</sup> AVSARTAN HCT 150/12.5 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 150/12.5 [WG]
			<sup>B</sup> 7.00	*25.89	20.34	<sup>a</sup> Avapro HCT 150/12.5 [AV]	<sup>a</sup> Karvezide 150/12.5 [SW]

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13545X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.21	22.66	<sup>a</sup> Abisart HCTZ 300/12.5 [AL] <sup>a</sup> AVSARTAN HCT 300/12.5 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 300/12.5 [WG]
			<sup>B</sup> 7.00	*28.21	22.66	<sup>a</sup> Avapro HCT 300/12.5 [AV]	<sup>a</sup> Karvezide 300/12.5 [SW]

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

13446Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.89	23.34	<sup>a</sup> Abisart HCTZ 300/25 [AL] <sup>a</sup> AVSARTAN HCT 300/25 [RF] <sup>a</sup> Irbesartan/HCT Sandoz [SZ]	<sup>a</sup> APO-Irbesartan HCTZ [TX] <sup>a</sup> Blooms the Chemist Irbesartan HCTZ 300/25 [IB] <sup>a</sup> IRBESARTAN HCTZ-WGR 300/25 [WG] <sup>a</sup> Karvezide 300/25 [SW]
			<sup>B</sup> 7.00	*28.89	23.34	<sup>a</sup> Avapro HCT 300/25 [AV]	

■ **OLMESARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2161R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Olmesartan/HCTZ 20/12.5 [TX] <sup>a</sup> OLMERTAN COMBI 20/12.5 [RW] <sup>a</sup> Olmesartan/HCT Sandoz [SZ] <sup>a</sup> Pharmacor Olmesartan HCTZ 20/12.5 [CR]	<sup>a</sup> APX-Olmesartan/HCTZ [TY] <sup>a</sup> Olmesartan HCT - MYL 20/12.5 [AF] <sup>a</sup> OLMESARTAN HCTZ-WGR 20/12.5 [WG]
			<sup>B</sup> 3.00	20.76	19.21	<sup>a</sup> Olmetec Plus [AL]	

**olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2166B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.36	20.81	<sup>a</sup> APO-Olmesartan/HCTZ 40/12.5 [TX] <sup>a</sup> OLMERTAN COMBI 40/12.5 [RW] <sup>a</sup> Olmesartan/HCT Sandoz [SZ] <sup>a</sup> Pharmacor Olmesartan HCTZ 40/12.5 [CR]	<sup>a</sup> APX-Olmesartan/HCTZ [TY] <sup>a</sup> Olmesartan HCT - MYL 40/12.5 [AF] <sup>a</sup> OLMESARTAN HCTZ-WGR 40/12.5 [WG]
			<sup>B</sup> 4.00	23.36	20.81	<sup>a</sup> Olmetec Plus [AL]	

**olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30**

2170F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.13	21.58	<sup>a</sup> APO-Olmesartan/HCTZ 40/25 [TX] <sup>a</sup> OLMERTAN COMBI 40/25 [RW] <sup>a</sup> Olmesartan/HCT Sandoz [SZ] <sup>a</sup> Pharmacor Olmesartan HCTZ 40/25 [CR]	<sup>a</sup> APX-Olmesartan/HCTZ [TY] <sup>a</sup> Olmesartan HCT - MYL 40/25 [AF] <sup>a</sup> OLMESARTAN HCTZ-WGR 40/25 [WG]
			<sup>B</sup> 4.00	24.13	21.58	<sup>a</sup> Olmetec Plus [AL]	

■ **OLMESARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13447R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Olmesartan/HCTZ 20/12.5 [TX] <sup>a</sup> OLMERTAN COMBI 20/12.5 [RW] <sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> APX-Olmesartan/HCTZ [TY] <sup>a</sup> Olmesartan HCT - MYL 20/12.5 [AF] <sup>a</sup> OLMESARTAN HCTZ-WGR 20/12.5 [WG]

<sup>a</sup> Pharmacor Olmesartan HCTZ  
20/12.5 [CR]

<sup>B</sup>6.00 \*28.07 23.52 <sup>a</sup> Olmetec Plus [AL]

### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

13601W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.27	26.72	<sup>a</sup> APO-Olmesartan/HCTZ 40/12.5 [TX]	<sup>a</sup> APX-Olmesartan/HCTZ [TY]
						<sup>a</sup> OLMERTAN COMBI 40/12.5 [RW]	<sup>a</sup> Olmesartan HCT - MYL 40/12.5 [AF]
						<sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> OLMESARTAN HCTZ-WGR 40/12.5 [WG]
						<sup>a</sup> Pharmacor Olmesartan HCTZ 40/12.5 [CR]	
						<sup>B</sup> 8.00 *33.27 26.72	<sup>a</sup> Olmetec Plus [AL]

### olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

13602X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*26.81	28.26	<sup>a</sup> APO-Olmesartan/HCTZ 40/25 [TX]	<sup>a</sup> APX-Olmesartan/HCTZ [TY]
						<sup>a</sup> OLMERTAN COMBI 40/25 [RW]	<sup>a</sup> Olmesartan HCT - MYL 40/25 [AF]
						<sup>a</sup> Olmesartan/HCT Sandoz [SZ]	<sup>a</sup> OLMESARTAN HCTZ-WGR 40/25 [WG]
						<sup>a</sup> Pharmacor Olmesartan HCTZ 40/25 [CR]	
						<sup>B</sup> 8.00 *34.81 28.26	<sup>a</sup> Olmetec Plus [AL]

## ■ TELMISARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

8622T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.29	17.74	<sup>a</sup> APO-Telmisartan HCTZ 40/12.5 [TX]	<sup>a</sup> Mizart HCT 40/12.5 mg [AF]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> TELMISARTAN HCTZ-WGR 40/12.5 [WG]
						<sup>a</sup> Teltartan HCT 40/12.5 [RW]	
						<sup>B</sup> 10.00 26.29 17.74	<sup>a</sup> Micardis Plus 40/12.5 mg [BY]

### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

8623W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Telmisartan HCTZ 80/12.5 [TX]	<sup>a</sup> Mizart HCT 80/12.5 mg [AF]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> TELMISARTAN HCTZ-WGR 80/12.5 [WG]
						<sup>a</sup> Teltartan HCT 80/12.5 [RW]	
						<sup>B</sup> 10.00 27.76 19.21	<sup>a</sup> Micardis Plus 80/12.5 mg [BY]

### telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

9381R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.09	19.54	<sup>a</sup> APO-Telmisartan HCTZ 80/25 [TX]	<sup>a</sup> Mizart HCT 80/25 mg [AF]
						<sup>a</sup> Telmisartan/HCT Sandoz [SZ]	<sup>a</sup> TELMISARTAN HCTZ-WGR 80/25 [WG]
						<sup>a</sup> Teltartan HCT 80/25 [RW]	
						<sup>B</sup> 10.00 28.09 19.54	<sup>a</sup> Micardis Plus 80/25 mg [BY]

## ■ TELMISARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13546Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.13	20.58	<sup>a</sup> APO-Telmisartan HCTZ 40/12.5 [TX] <sup>a</sup> Telmisartan/HCT Sandoz [SZ] <sup>a</sup> Teltartan HCT 40/12.5 [RW]	<sup>a</sup> Mizart HCT 40/12.5 mg [AF] <sup>a</sup> TELMISARTAN HCTZ-WGR 40/12.5 [WG]
			<sup>B</sup> 20.00	*39.13	20.58	<sup>a</sup> Micardis Plus 40/12.5 mg [BY]	

**telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13574K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APO-Telmisartan HCTZ 80/12.5 [TX] <sup>a</sup> Telmisartan/HCT Sandoz [SZ] <sup>a</sup> Teltartan HCT 80/12.5 [RW]	<sup>a</sup> Mizart HCT 80/12.5 mg [AF] <sup>a</sup> TELMISARTAN HCTZ-WGR 80/12.5 [WG]
			<sup>B</sup> 20.00	*42.07	23.52	<sup>a</sup> Micardis Plus 80/12.5 mg [BY]	

**telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28**

13607E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.73	24.18	<sup>a</sup> APO-Telmisartan HCTZ 80/25 [TX] <sup>a</sup> Telmisartan/HCT Sandoz [SZ] <sup>a</sup> Teltartan HCT 80/25 [RW]	<sup>a</sup> Mizart HCT 80/25 mg [AF] <sup>a</sup> TELMISARTAN HCTZ-WGR 80/25 [WG]
			<sup>B</sup> 20.00	*42.73	24.18	<sup>a</sup> Micardis Plus 80/25 mg [BY]	

**■ VALSARTAN + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9373H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.71	23.16	<sup>a</sup> Co-Diovan 160/12.5 [NV]	<sup>a</sup> Dilart HCT 160/12.5 [AF]

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

9374J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.81	24.26	<sup>a</sup> Co-Diovan 160/25 [NV]	<sup>a</sup> Dilart HCT 160/25 [AF]

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

9372G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.13	21.58	<sup>a</sup> Co-Diovan 80/12.5 [NV]	<sup>a</sup> Dilart HCT 80/12.5 [AF]

**■ VALSARTAN + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13606D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.97	31.42	<sup>a</sup> Co-Diovan 160/12.5 [NV]	<sup>a</sup> Dilart HCT 160/12.5 [AF]

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

13453C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*32.17	31.60	<sup>a</sup> Co-Diovan 160/25 [NV]	<sup>a</sup> Dilart HCT 160/25 [AF]

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

13393X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*26.81	28.26	<sup>a</sup> Co-Diovan 80/12.5 [NV]	<sup>a</sup> Dilart HCT 80/12.5 [AF]

## ■ VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

### Restricted benefit

Hypertension

### **Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

9481B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.73	25.18	<sup>a</sup> Co-Diovan 320/12.5 [NV]	<sup>a</sup> Dilart HCT 320/12.5 [AF]

### valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

9482C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.82	26.27	<sup>a</sup> Co-Diovan 320/25 [NV]	<sup>a</sup> Dilart HCT 320/25 [AF]

## ■ VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

### Restricted benefit

Hypertension

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

13517K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.01	31.60	<sup>a</sup> Co-Diovan 320/12.5 [NV]	<sup>a</sup> Dilart HCT 320/12.5 [AF]

### valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

13455E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*36.19	31.60	<sup>a</sup> Co-Diovan 320/25 [NV]	<sup>a</sup> Dilart HCT 320/25 [AF]

### Angiotensin II receptor blockers (ARBs) and calcium channel blockers

## ■ AMLODIPINE + VALSARTAN

### Restricted benefit

Hypertension

### **Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

### amlodipine 10 mg + valsartan 160 mg tablet, 28

9377M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.00	25.45	<sup>a</sup> Amlodipine/Valsartan Novartis 10/160 [NM]
			<sup>B</sup> 6.00	30.00	25.45	<sup>a</sup> Exforge 10/160 [NV]

### amlodipine 10 mg + valsartan 320 mg tablet, 28

5460J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.27	27.72	<sup>a</sup> Amlodipine/Valsartan Novartis 10/320 [NM]
			<sup>B</sup> 6.00	32.27	27.72	<sup>a</sup> Exforge 10/320 [NV]

### amlodipine 5 mg + valsartan 160 mg tablet, 28

9376L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.47	24.92	<sup>a</sup> Amlodipine/Valsartan Novartis 5/160 [NM]
			<sup>B</sup> 6.00	29.47	24.92	<sup>a</sup> Exforge 5/160 [NV]

### amlodipine 5 mg + valsartan 320 mg tablet, 28

5459H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.06	27.51	<sup>a</sup> Amlodipine/Valsartan Novartis 5/320 [NM]

			<sup>B</sup> 6.00	32.06	27.51	<sup>a</sup> Exforge 5/320 [NV]	
<b>amlodipine 5 mg + valsartan 80 mg tablet, 28</b>							
9375K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	5	..	21.44	22.89	<sup>a</sup> Amlodipine/Valsartan Novartis 5/80 [NM]	
			<sup>B</sup> 6.00	27.44	22.89	<sup>a</sup> Exforge 5/80 [NV]	

## ■ AMLODIPINE + VALSARTAN

### Restricted benefit

Hypertension

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

### amlodipine 10 mg + valsartan 160 mg tablet, 28

13454D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*34.55	31.60	<sup>a</sup> Amlodipine/Valsartan Novartis 10/160 [NM]	
			<sup>B</sup> 12.00	*46.55	31.60	<sup>a</sup> Exforge 10/160 [NV]	

### amlodipine 10 mg + valsartan 320 mg tablet, 28

13389Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*39.09	31.60	<sup>a</sup> Amlodipine/Valsartan Novartis 10/320 [NM]	
			<sup>B</sup> 12.00	*51.09	31.60	<sup>a</sup> Exforge 10/320 [NV]	

### amlodipine 5 mg + valsartan 160 mg tablet, 28

13516J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*33.49	31.60	<sup>a</sup> Amlodipine/Valsartan Novartis 5/160 [NM]	
			<sup>B</sup> 12.00	*45.49	31.60	<sup>a</sup> Exforge 5/160 [NV]	

### amlodipine 5 mg + valsartan 320 mg tablet, 28

13604B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*38.67	31.60	<sup>a</sup> Amlodipine/Valsartan Novartis 5/320 [NM]	
			<sup>B</sup> 12.00	*50.67	31.60	<sup>a</sup> Exforge 5/320 [NV]	

### amlodipine 5 mg + valsartan 80 mg tablet, 28

13421J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*29.43	30.88	<sup>a</sup> Amlodipine/Valsartan Novartis 5/80 [NM]	
			<sup>B</sup> 12.00	*41.43	30.88	<sup>a</sup> Exforge 5/80 [NV]	

## ■ OLMESARTAN + AMLODIPINE

### Restricted benefit

Hypertension

### Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

### olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

5293N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.03	20.48	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 40/5 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 40/5 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/5 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 40/5 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 40/5 [CR]	
			<sup>B</sup> 3.00	22.03	20.48	<sup>a</sup> Sevikar 40/5 [AL]	



**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

5292M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.35	18.80	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 20/5 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 20/5 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 20/5 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 20/5 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 20/5 [CR]	
			<sup>B</sup> 4.00	21.35	18.80	<sup>a</sup> Sevikar 20/5 [AL]	

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

5294P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.44	20.89	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 40/10 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 40/10 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/10 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 40/10 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 40/10 [CR]	
			<sup>B</sup> 3.00	22.44	20.89	<sup>a</sup> Sevikar 40/10 [AL]	

**■ OLMESARTAN + AMLODIPINE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

13449W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.25	22.70	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 20/5 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 20/5 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 20/5 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 20/5 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 20/5 [CR]	
			<sup>B</sup> 8.00	*29.25	22.70	<sup>a</sup> Sevikar 20/5 [AL]	

**■ OLMESARTAN + AMLODIPINE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30**

13964Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.61	26.06	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 40/5 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 40/5 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/5 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 40/5 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 40/5 [CR]	
			<sup>B</sup> 6.00	*30.61	26.06	<sup>a</sup> Sevikar 40/5 [AL]	

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

13943W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.43	26.88	<sup>a</sup> APO-OLMESARTAN/AMLODIPINE 40/10 [TY]	<sup>a</sup> OLMEKAR [RW]
						<sup>a</sup> Olmesartan/Amlodipine 40/10 APOTEX [TX]	<sup>a</sup> Olmesartan/Amlodipine - MYL 40/10 [AF]
						<sup>a</sup> Olmesartan/Amlodipine Sandoz [SZ]	<sup>a</sup> OLMESARTAN AMLODIPINE-WGR 40/10 [WG]
						<sup>a</sup> Pharmacor Olmesartan Amlodipine 40/10 [CR]	
			<sup>B</sup> 6.00	*31.43	26.88	<sup>a</sup> Sevikar 40/10 [AL]	

**■ TELMISARTAN + AMLODIPINE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

8979N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 5.49	22.71	18.67	<sup>a</sup> Twynsta [BY]

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

8978M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.60	18.05	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 5.53	22.13	18.05	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

8981Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.07	21.52	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 5.30	25.37	21.52	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

8980P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.43	20.88	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 5.30	24.73	20.88	<sup>a</sup> Twynsta [BY]

**■ TELMISARTAN + AMLODIPINE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

13515H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 10.98	*31.97	22.44	<sup>a</sup> Twynsta [BY]

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

13483P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*19.75	21.20	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 11.06	*30.81	21.20	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

13451Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*26.69	28.14	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 10.60	*37.29	28.14	<sup>a</sup> Twynsta [BY]

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

13450X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.41	26.86	<sup>a</sup> Pritor/Amlodipine [FI]
			<sup>B</sup> 10.60	*36.01	26.86	<sup>a</sup> Twynsta [BY]

*Angiotensin II receptor blockers (ARBs), other combinations*

## ■ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

### amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

5287G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.51	26.96	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM]
			<sup>B</sup> 6.00	31.51	26.96	<sup>a</sup> Exforge HCT 10/160/12.5 [NV]

### amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

5288H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.03	28.48	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM]
			<sup>B</sup> 12.00	39.03	28.48	<sup>a</sup> Exforge HCT 10/160/25 [NV]

### amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

5289J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	29.30	30.75	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM]
			<sup>B</sup> 6.00	35.30	30.75	<sup>a</sup> Exforge HCT 10/320/25 [NV]

### amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

5285E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.99	26.44	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM]
			<sup>B</sup> 12.00	36.99	26.44	<sup>a</sup> Exforge HCT 5/160/12.5 [NV]

### amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

5286F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.50	27.95	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM]
			<sup>B</sup> 6.00	32.50	27.95	<sup>a</sup> Exforge HCT 5/160/25 [NV]

## ■ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

### Restricted benefit

Hypertension

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

### amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

13514G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*37.57	31.60	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM]
			<sup>B</sup> 12.00	*49.57	31.60	<sup>a</sup> Exforge HCT 10/160/12.5 [NV]

### amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

13390R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*40.61	31.60	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM]
			<sup>B</sup> 24.00	*64.61	31.60	<sup>a</sup> Exforge HCT 10/160/25 [NV]

### amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

13573J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.15	31.60	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM]
			<sup>B</sup> 12.00	*57.15	31.60	<sup>a</sup> Exforge HCT 10/320/25 [NV]

### amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

13448T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*36.53	31.60	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM]
			<sup>B</sup> 24.00	*60.53	31.60	<sup>a</sup> Exforge HCT 5/160/12.5 [NV]

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

13603Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*39.55	31.60	<sup>a</sup> Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM]	
			<sup>B</sup> 12.00	*51.55	31.60	<sup>a</sup> Exforge HCT 5/160/25 [NV]	

**■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

10005N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.45	20.90	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]	<sup>a</sup> Olamlo HCT 20/5/12.5 [AL]
						<sup>a</sup> Olmekar HCT 20/5/12.5 [RF]	
			<sup>B</sup> 3.00	22.45	20.90	<sup>a</sup> Sevikar HCT 20/5/12.5 [AF]	

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2880N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.29	23.74	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX]	<sup>a</sup> Olamlo HCT 40/5/12.5 [AL]
						<sup>a</sup> Olmekar HCT 40/5/12.5 [RF]	
			<sup>B</sup> 2.62	24.91	23.74	<sup>a</sup> Sevikar HCT 40/5/12.5 [AF]	

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

2836G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.70	24.15	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX]	<sup>a</sup> Olamlo HCT 40/10/12.5 [AL]
						<sup>a</sup> Olmekar HCT 40/10/12.5 [RF]	
			<sup>B</sup> 4.26	26.96	24.15	<sup>a</sup> Sevikar HCT 40/10/12.5 [AF]	

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

2864R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	23.85	25.30	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX]	<sup>a</sup> Olamlo HCT 40/5/25 [AL]
						<sup>a</sup> Olmekar HCT 40/5/25 [RF]	
			<sup>B</sup> 2.67	26.52	25.30	<sup>a</sup> Sevikar HCT 40/5/25 [AF]	

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

2953K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	24.23	25.68	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]	<sup>a</sup> Olamlo HCT 40/10/25 [AL]
						<sup>a</sup> Olmekar HCT 40/10/25 [RF]	
			<sup>B</sup> 2.67	26.90	25.68	<sup>a</sup> Sevikar HCT 40/10/25 [AF]	

**■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13481M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.45	26.90	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX]	<sup>a</sup> Olamlo HCT 20/5/12.5 [AL]
						<sup>a</sup> Olmekar HCT 20/5/12.5 [RF]	
			<sup>B</sup> 6.00	*31.45	26.90	<sup>a</sup> Sevikar HCT 20/5/12.5 [AF]	

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13513F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.13	31.60	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX]	<sup>a</sup> Olamlo HCT 40/5/12.5 [AL]
			<sup>B</sup> 5.24	*36.37	31.60	<sup>a</sup> Olmekar HCT 40/5/12.5 [RF]	<sup>a</sup> Sevikar HCT 40/5/12.5 [AF]

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

13482N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.95	31.60	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX]	<sup>a</sup> Olamlo HCT 40/10/12.5 [AL]
			<sup>B</sup> 8.52	*40.47	31.60	<sup>a</sup> Olmekar HCT 40/10/12.5 [RF]	<sup>a</sup> Sevikar HCT 40/10/12.5 [AF]

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

13512E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.25	31.60	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX]	<sup>a</sup> Olamlo HCT 40/5/25 [AL]
			<sup>B</sup> 5.34	*39.59	31.60	<sup>a</sup> Olmekar HCT 40/5/25 [RF]	<sup>a</sup> Sevikar HCT 40/5/25 [AF]

**■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

14002Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*35.01	31.60	<sup>a</sup> APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]	<sup>a</sup> Olamlo HCT 40/10/25 [AL]
			<sup>B</sup> 5.34	*40.35	31.60	<sup>a</sup> Olmekar HCT 40/10/25 [RF]	<sup>a</sup> Sevikar HCT 40/10/25 [AF]

**■ SACUBITRIL + VALSARTAN****Authority required (STREAMLINED)****11680**

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

11123K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.26	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

11131W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.26	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

11122J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.26	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**■ SACUBITRIL + VALSARTAN****Authority required (STREAMLINED)****14254**

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

13570F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*190.75	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

13511D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*190.75	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

13445P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*190.75	31.60	<sup>a</sup> Entresto [NV]	<sup>a</sup> Pharmacor Sacubitril/Valsartan [CR]
						<sup>a</sup> Valtresto [RM]	

**■ LIPID MODIFYING AGENTS****LIPID MODIFYING AGENTS, PLAIN***HMG CoA reductase inhibitors***■ ATORVASTATIN****atorvastatin 10 mg tablet, 30**

8213G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 10 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**atorvastatin 20 mg tablet, 30**

8214H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.27	17.72	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 20 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**atorvastatin 40 mg tablet, 30**

8215J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.17	18.62	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 40 [AF]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

<sup>a</sup> Trovas [RA]**atorvastatin 80 mg tablet, 30**

8521L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 80 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**■ ATORVASTATIN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atorvastatin 10 mg tablet, 30**

13495G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 10 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**atorvastatin 20 mg tablet, 30**

13529C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.09	20.54	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 20 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**atorvastatin 40 mg tablet, 30**

13468W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.89	22.34	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 40 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**atorvastatin 80 mg tablet, 30**

13374X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-Atorvastatin [TX] <sup>a</sup> Atorvastatin SZ [HX] <sup>a</sup> BTC Atorvastatin [BG] <sup>a</sup> Lorstat 80 [AF] <sup>a</sup> Trovas [RA]	<sup>a</sup> Atorvachol [RF] <sup>a</sup> ATORVASTATIN-WGR [WG] <sup>a</sup> Lipitor [AS] <sup>a</sup> Pharmacor Atorvastatin [CR]

**■ FLUVASTATIN****fluvastatin 80 mg modified release tablet, 28**

2863Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.09	31.60	Lescol XL [NV]

**■ FLUVASTATIN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluvastatin 80 mg modified release tablet, 28**

13558N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*60.73	31.60	Lescol XL [NV]

**■ PRAVASTATIN****pravastatin sodium 10 mg tablet, 30**

2833D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Lipostat 10 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]
			<sup>b</sup> 2.93	19.10	17.62	<sup>a</sup> Cholstat 10 [AF]	
			<sup>b</sup> 4.95	21.12	17.62	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 20 mg tablet, 30**

2834E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.44	17.89	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Lipostat 20 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]	<sup>a</sup> Cholstat 20 [AF] <sup>a</sup> Pravastatin Sandoz [SZ]
			<sup>B</sup> 4.98	21.42	17.89	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 40 mg tablet, 30**

8197K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.26	18.71	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Lipostat 40 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]	<sup>a</sup> Cholstat 40 [AF] <sup>a</sup> Pravastatin Sandoz [SZ]
			<sup>B</sup> 4.98	22.24	18.71	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 80 mg tablet, 30**

8829Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.30	20.75	<sup>a</sup> APX-Pravastatin [TY]	<sup>a</sup> Lipostat 80 [RF]
			<sup>B</sup> 5.15	24.45	20.75	<sup>a</sup> Pravachol [RW]	

**■ PRAVASTATIN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pravastatin sodium 10 mg tablet, 30**

13496H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Pravastatin Sandoz [SZ]	<sup>a</sup> Lipostat 10 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]
			<sup>B</sup> 5.86	*24.75	20.34	<sup>a</sup> Cholstat 10 [AF]	
			<sup>B</sup> 9.90	*28.79	20.34	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 20 mg tablet, 30**

13497J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.43	20.88	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Lipostat 20 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]	<sup>a</sup> Cholstat 20 [AF] <sup>a</sup> Pravastatin Sandoz [SZ]
			<sup>B</sup> 9.96	*29.39	20.88	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 40 mg tablet, 30**

13432Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.07	22.52	<sup>a</sup> APX-Pravastatin [TY] <sup>a</sup> Lipostat 40 [RF] <sup>a</sup> PRAVASTATIN-WGR [WG]	<sup>a</sup> Cholstat 40 [AF] <sup>a</sup> Pravastatin Sandoz [SZ]
			<sup>B</sup> 9.96	*31.03	22.52	<sup>a</sup> Pravachol [RW]	

**pravastatin sodium 80 mg tablet, 30**

13527Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.15	26.60	<sup>a</sup> APX-Pravastatin [TY]	<sup>a</sup> Lipostat 80 [RF]
			<sup>B</sup> 10.30	*35.45	26.60	<sup>a</sup> Pravachol [RW]	

**■ ROSUVASTATIN****rosuvastatin 10 mg tablet, 30**

2628H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 10 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 10 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 4.94	22.16	18.67	<sup>a</sup> Crestor [FK]	

**rosuvastatin 20 mg tablet, 30**

2574L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.28	18.73	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 20 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 20 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]



			<sup>B</sup> 4.94	22.22	18.73	<sup>a</sup> Crestor [FK]	
<b>rosuvastatin 40 mg tablet, 30</b>							
2594M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.90	20.35	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 40 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 40 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 4.94	23.84	20.35	<sup>a</sup> Crestor [FK]	

<b>rosuvastatin 5 mg tablet, 30</b>							
2606E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 5 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 5 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 4.93	21.10	17.62	<sup>a</sup> Crestor [FK]	

## ■ ROSUVASTATIN

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

<b>rosuvastatin 10 mg tablet, 30</b>							
13586C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 10 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 10 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 9.88	*30.87	22.44	<sup>a</sup> Crestor [FK]	

<b>rosuvastatin 20 mg tablet, 30</b>							
13588E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.11	22.56	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 20 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 20 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 9.88	*30.99	22.56	<sup>a</sup> Crestor [FK]	

<b>rosuvastatin 40 mg tablet, 30</b>							
13589F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.35	25.80	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 40 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 40 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 9.88	*34.23	25.80	<sup>a</sup> Crestor [FK]	

<b>rosuvastatin 5 mg tablet, 30</b>							
13406N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-ROSUVASTATIN [TX] <sup>a</sup> Blooms Rosuvastatin [BG] <sup>a</sup> Crosuva 5 [RW]  <sup>a</sup> Rosuvastatin APOTEX [GX] <sup>a</sup> Rosuvastatin RBX [RA] <sup>a</sup> ROSUVASTATIN-WGR [WG]	<sup>a</sup> APX-Rosuvastatin [TY] <sup>a</sup> Cavstat [AF] <sup>a</sup> Pharmacor Rosuvastatin 5 [CR] <sup>a</sup> Rosuvastatin Lupin [GQ] <sup>a</sup> Rosuvastatin Sandoz [SZ]
			<sup>B</sup> 9.86	*28.75	20.34	<sup>a</sup> Crestor [FK]	

## ■ SIMVASTATIN

### simvastatin 10 mg tablet, 30

2011W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 10 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]

### simvastatin 20 mg tablet, 30

2012X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 20 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]
			<sup>b</sup> 9.28	25.45	17.62	<sup>a</sup> Lipex 20 [AL]	<sup>a</sup> Zocor [MQ]

### simvastatin 40 mg tablet, 30

8173E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.34	17.79	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 40 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]
			<sup>b</sup> 9.24	25.58	17.79	<sup>a</sup> Lipex 40 [AL]	<sup>a</sup> Zocor [MQ]

### simvastatin 5 mg tablet, 30

2013Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> Simvastatin Sandoz [SZ]	<sup>a</sup> Zimstat [AF]

### simvastatin 80 mg tablet, 30

8313M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 80 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]

## ■ SIMVASTATIN

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### simvastatin 10 mg tablet, 30

13528B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 10 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]

### simvastatin 20 mg tablet, 30

13373W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 20 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]
			<sup>b</sup> 18.56	*37.45	20.34	<sup>a</sup> Lipex 20 [AL]	<sup>a</sup> Zocor [MQ]

### simvastatin 40 mg tablet, 30

13471B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*19.23	20.68	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 40 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]
			<sup>b</sup> 18.48	*37.71	20.68	<sup>a</sup> Lipex 40 [AL]	<sup>a</sup> Zocor [MQ]

### simvastatin 5 mg tablet, 30

13559P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.89	20.34	<sup>a</sup> Simvastatin Sandoz [SZ]	<sup>a</sup> Zimstat [AF]

### simvastatin 80 mg tablet, 30

13498K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*20.99	22.44	<sup>a</sup> APO-Simvastatin [TX] <sup>a</sup> Simvastatin Sandoz [SZ] <sup>a</sup> Zimstat [AF]	<sup>a</sup> Simvar 80 [RW] <sup>a</sup> SIMVASTATIN-WGR [WG]

## Fibrates

## ■ FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high

cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**fenofibrate 145 mg tablet, 30**

9023X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.93	22.38	<sup>a</sup> APO-Fenofibrate [TX] <sup>a</sup> Fenocol [XT] <sup>a</sup> Fenofibrate Lupin [GQ] <sup>a</sup> Fenofibrate Sandoz [SZ] <sup>a</sup> FENOFIBRATE-WGR [WG]	<sup>a</sup> BTC Fenofibrate [BG] <sup>a</sup> Fenofibrate Cipla [LR] <sup>a</sup> FENOFIBRATE RBX [RA] <sup>a</sup> Fenofibrate Viatris [AL] <sup>a</sup> Lipidil [GO]

**fenofibrate 48 mg tablet, 60**

9022W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.45	19.90	<sup>a</sup> APO-Fenofibrate [TX] <sup>a</sup> Fenofibrate Lupin [GQ] <sup>a</sup> Fenofibrate Viatris [AL] <sup>a</sup> Lipidil [GO]	<sup>a</sup> Fenofibrate Cipla [LR] <sup>a</sup> FENOFIBRATE RBX [RA] <sup>a</sup> FENOFIBRATE-WGR [WG]

▪ **FENOFIBRATE**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fenofibrate 145 mg tablet, 30**

13587D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.41	29.86	<sup>a</sup> APO-Fenofibrate [TX] <sup>a</sup> Fenocol [XT] <sup>a</sup> Fenofibrate Lupin [GQ] <sup>a</sup> Fenofibrate Sandoz [SZ] <sup>a</sup> FENOFIBRATE-WGR [WG]	<sup>a</sup> BTC Fenofibrate [BG] <sup>a</sup> Fenofibrate Cipla [LR] <sup>a</sup> FENOFIBRATE RBX [RA] <sup>a</sup> Fenofibrate Viatris [AL] <sup>a</sup> Lipidil [GO]

**fenofibrate 48 mg tablet, 60**

13469X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.45	24.90	<sup>a</sup> APO-Fenofibrate [TX] <sup>a</sup> Fenofibrate Lupin [GQ] <sup>a</sup> Fenofibrate Viatris [AL] <sup>a</sup> Lipidil [GO]	<sup>a</sup> Fenofibrate Cipla [LR] <sup>a</sup> FENOFIBRATE RBX [RA] <sup>a</sup> FENOFIBRATE-WGR [WG]

▪ **GEMFIBROZIL**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**gemfibrozil 600 mg tablet, 60**

1453L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.36	24.81	<sup>a</sup> Ausgem [RW]	<sup>a</sup> Lipigem [AF]

▪ **GEMFIBROZIL**

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**gemfibrozil 600 mg tablet, 60**

13618R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*33.27	31.60	<sup>a</sup> Ausgem [RW]	<sup>a</sup> Lipigem [AF]

*Bile acid sequestrants*

▪ **COLESTYRAMINE**

**colestyramine 4 g powder for oral liquid, 50 sachets**

2967E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*82.89	31.60	Questran Lite [GO]

## ■ COLESTYRAMINE

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### colestyramine 4 g powder for oral liquid, 50 sachets

14477Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*154.23	31.60	Questran Lite [GO]

### *Other lipid modifying agents*

## ■ EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**15432**

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

### **Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

- Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The following must be documented in the patient's medical records:

- the qualifying Dutch Lipid Clinic Network Score; or
  - the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia
- One of the following must be documented in the patient's medical records regarding prior statin treatment:

- the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
- the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

### evolocumab 140 mg/mL injection, 1 mL pen device

10958R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*504.66	31.60	Repatha [AN]

## ■ EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**10388**

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**evolocumab 140 mg/mL injection, 1 mL pen device**

11977J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*504.66	31.60	Repatha [AN]

**■ EVOLOCUMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****16294**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreatment should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreatment should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be documented in the patient's medical records:

- (i) the qualifying Dutch Lipid Clinic Network Score; or
- (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

- (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
- (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**Authority required (STREAMLINED)**

**16351**

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreat should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreat should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years of more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

#### evolocumab 140 mg/mL injection, 1 mL pen device

11484K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*339.25	31.60	Repatha [AN]

#### ■ EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

##### **16336**

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

##### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

##### Authority required (STREAMLINED)

##### **16350**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

##### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

#### evolocumab 140 mg/mL injection, 1 mL pen device

11985T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*339.25	31.60	Repatha [AN]

#### ■ EZETIMIBE

**Note** Pharmaceutical benefits that have the form ezetimibe tablet 10 mg can be substituted for Ezetimibe USP (Camber, USA) in the case of a shortage.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ezetimibe 10 mg tablet, 30**

8757X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.10	20.55	<sup>a</sup> APO-Ezetimibe [TX] <sup>a</sup> EZEMICHOL [RW] <sup>a</sup> Ezetimibe Sandoz [SZ] <sup>a</sup> Pharmacor Ezetimibe 10 [CR]	<sup>a</sup> BTC Ezetimibe [BG] <sup>a</sup> Ezetimibe GH [GQ] <sup>a</sup> EZETIMIBE-WGR [WG] <sup>a</sup> Zient 10mg [AF]
			<sup>B</sup> 2.16	21.26	20.55	<sup>a</sup> Ezetrol [AL]	

**ezetimibe 10 mg tablet, 90**

14682R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.33	5	..	*29.69	31.14	<sup>a</sup> Ezetimibe USP (Camber, USA) [RQ]

**■ EZETIMIBE**

**Note** Pharmaceutical benefits that have the form ezetimibe tablet 10 mg can be substituted for Ezetimibe USP (Camber, USA) in the case of a shortage.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg tablet, 30**

13440J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.75	26.20	<sup>a</sup> APO-Ezetimibe [TX] <sup>a</sup> EZEMICHOL [RW] <sup>a</sup> Ezetimibe Sandoz [SZ] <sup>a</sup> Pharmacor Ezetimibe 10 [CR]	<sup>a</sup> BTC Ezetimibe [BG] <sup>a</sup> Ezetimibe GH [GQ] <sup>a</sup> EZETIMIBE-WGR [WG] <sup>a</sup> Zient 10mg [AF]
			<sup>B</sup> 4.32	*29.07	26.20	<sup>a</sup> Ezetrol [AL]	

**ezetimibe 10 mg tablet, 90**

14668B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.67	5	..	*35.63	31.60	<sup>a</sup> Ezetimibe USP (Camber, USA) [RQ]

**■ ICOSAPENT ETHYL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15889**

Established atherosclerotic cardiovascular disease with hypertriglyceridaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have at least one of (i) coronary artery disease, (ii) cerebrovascular or carotid disease, (iii) peripheral arterial disease, **AND**
- Patient must be treated with a stable dose of a HMG CoA reductase inhibitor (statin) to achieve target secondary prevention LDL-c levels for at least 12 consecutive weeks; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have LDL cholesterol level between 1.0 millimoles per litre and 2.6 millimoles per litre; OR
- Patient must have a non-HDL cholesterol between 1.5 millimoles per litre and 3.5 millimoles per litre if LDL cannot be measured/detected, **AND**
- Patient must have fasting triglyceride level between 1.7 millimoles per litre and 5.6 millimoles per litre.

The qualifying fasting triglyceride level and LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, dietary therapy and exercise should be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or



(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Atherosclerotic cardiovascular disease is defined as:

(i) Documented coronary artery disease (CAD); one or more of the following primary criteria must have been satisfied:

a) Documented multi-vessel CAD (at least 50% stenosis in at least two major epicardial coronary arteries, with or without antecedent revascularisation).

b) Documented prior MI.

c) Hospitalisation for high-risk non-ST-segment elevation acute coronary syndrome, with objective evidence of ischemia: ST-segment deviation or biomarker positivity.

(ii) Documented cerebrovascular or carotid disease; one of the following primary criteria must have been satisfied:

a) Documented prior ischemic stroke.

b) Symptomatic carotid artery disease with at least 50% carotid arterial stenosis.

c) Asymptomatic carotid artery disease with at least 70% carotid arterial stenosis per angiography or duplex ultrasound.

d) History of carotid revascularisation (catheter-based or surgical).

(iii) Documented peripheral arterial disease; one or more of the following primary criteria must have been satisfied:

a) Ankle brachial index (ABI) less than 0.9 with symptoms of intermittent claudication.

b) History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).

#### **Authority required (STREAMLINED)**

**15927**

Established atherosclerotic cardiovascular disease with hypertriglyceridaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with a HMG CoA reductase inhibitor (statin), unless the patient is contraindicated to statins or has developed statin related adverse events necessitating withdrawal of statin treatment.

#### **icosapent ethyl 998 mg capsule, 120**

14617H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	154.10	31.60	Vazkepa [CS]

#### **■ INCLISIRAN**

**Note** Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab.

**Note** Authority applications for increased repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**16320**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

#### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

#### **Authority required (STREAMLINED)**

**16356**

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe**

14087K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1849.47	31.60	Leqvio [NV]

**■ INCLISIRAN**

**Note** Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16295**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreat should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreat should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be documented in the patient's medical records:

- (i) the qualifying Dutch Lipid Clinic Network Score; or
  - (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia
- One of the following must be documented in the patient's medical records regarding prior statin treatment:

- (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
- (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**Authority required (STREAMLINED)**

**16331**

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreatment should occur after a washout

period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreatment should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

### inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14101E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	1849.47	31.60	Leqvio [NV]

### ■ INCLISIRAN

**Note** Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### Authority required (STREAMLINED)

#### **16352**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR
- Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

#### **Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreatment should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retreatment should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be documented in the patient's medical records:

- (i) the qualifying Dutch Lipid Clinic Network Score; or
- (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

- (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
- (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

#### **Authority required (STREAMLINED)**

**16312**

Non-familial hypercholesterolaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus and be aged 60 years or more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; OR
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
- (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
- (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreatment should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retreatment should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

- (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
- (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

- (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or
- (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or
- (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or
- (iv) diabetes mellitus with microalbuminuria; or
- (v) diabetes mellitus and age 60 years or more; or
- (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or
- (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14152W NP	1	..	..	1849.47	31.60	Leqvio [NV]

**LIPID MODIFYING AGENTS, COMBINATIONS***Combinations of various lipid modifying agents***■ EZETIMIBE (&) ROSUVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10208G NP	±1	5	..	26.41	27.86	<sup>a</sup> Ezalo Composite Pack 10mg+10mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg [SZ]
			<sup>B</sup> 2.97	29.38	27.86	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10201X NP	±1	5	..	28.38	29.83	<sup>a</sup> Ezalo Composite Pack 10mg+20mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg [SZ]
			<sup>B</sup> 2.98	31.36	29.83	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10207F NP	±1	5	..	28.07	29.52	<sup>a</sup> Ezalo Composite Pack 10mg+40mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg [SZ]
			<sup>B</sup> 3.09	31.16	29.52	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10204C NP	±1	5	..	25.02	26.47	<sup>a</sup> Ezalo Composite Pack 10mg+5mg [AF] <sup>a</sup> Rosuzet Composite Pack [AL]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg [SZ]
			<sup>B</sup> 2.87	27.89	26.47		

**■ EZETIMIBE (&) ROSUVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13569E NP	±2	5	..	*39.37	31.60	<sup>a</sup> Ezalo Composite Pack 10mg+10mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg [SZ]
			<sup>B</sup> 5.94	*45.31	31.60	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13480L NP	±2	5	..	*43.31	31.60	<sup>a</sup> Ezalo Composite Pack 10mg+20mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg [SZ]
			<sup>B</sup> 5.96	*49.27	31.60	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13537L NP	±2	5	..	*42.69	31.60	<sup>a</sup> Ezalo Composite Pack 10mg+40mg [AF] <sup>a</sup> Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg [SZ]
			<sup>B</sup> 6.18	*48.87	31.60	<sup>a</sup> Rosuzet Composite Pack [AL]	

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13629H NP	±2	5	..	*36.59	31.60	<sup>a</sup> Ezalo Composite Pack 10mg+5mg [AF] <sup>a</sup> Rosuzet Composite Pack [AL]	<sup>a</sup> Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg [SZ]

**■ EZETIMIBE + ATORVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10392Y NP	1	5	..	20.95	22.40	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/10 [GQ]	<sup>a</sup> Ezetast [XT]

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10393B NP	1	5	..	21.51	22.96	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/20 [GQ]	<sup>a</sup> Ezetast [XT]

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10377E NP	1	5	..	24.57	26.02	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/40 [GQ]	<sup>a</sup> Ezetast [XT]

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10376D NP	1	5	..	27.38	28.83	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/80 [GQ]	<sup>a</sup> Ezetast [XT]

**■ EZETIMIBE + ATORVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13539N NP	2	5	..	*28.45	29.90	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/10 [GQ]	<sup>a</sup> Ezetast [XT]

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13622Y NP	2	5	..	*29.57	31.02	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/20 [GQ]	<sup>a</sup> Ezetast [XT]

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13416D NP	2	5	..	*35.69	31.60	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/40 [GQ]	<sup>a</sup> Ezetast [XT]



**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

13538M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*41.31	31.60	<sup>a</sup> Atozet [AF] <sup>a</sup> Ezetimibe/Atorvastatin GH 10/80 [GQ]	<sup>a</sup> Ezetast [XT]

**■ EZETIMIBE + SIMVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

9483D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.80	23.25	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/10 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/10 [WG] <sup>a</sup> EzSimva GH 10/10 [GQ]  <sup>a</sup> Vytorin [AL] <sup>a</sup> Zimybe 10/10 [MQ]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/10 [CR] <sup>a</sup> Zeklen 10/10 mg [AF]

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

9484E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.22	23.67	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/20 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/20 [WG] <sup>a</sup> EzSimva GH 10/20 [GQ]  <sup>a</sup> Vytorin [AL] <sup>a</sup> Zimybe 10/20 [MQ]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/20 [CR] <sup>a</sup> Zeklen 10/20 mg [AF]

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

8881K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.81	24.26	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/40 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/40 [WG] <sup>a</sup> EzSimva GH 10/40 [GQ]  <sup>a</sup> Zeklen 10/40 mg [AF]  <sup>B</sup> 2.00 24.81 24.26 <sup>a</sup> Vytorin [AL]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/40 [CR] <sup>a</sup> Zimybe 10/40 [MQ]

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

8882L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.64	25.09	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/80 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/80 [WG] <sup>a</sup> EzSimva GH 10/80 [GQ]  <sup>a</sup> Zeklen 10/80 mg [AF]  <sup>B</sup> 2.00 25.64 25.09 <sup>a</sup> Vytorin [AL]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/80 [CR] <sup>a</sup> Zimybe 10/80 [MQ]

**■ EZETIMIBE + SIMVASTATIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

13385L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*30.15	31.60	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/10 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/10 [WG] <sup>a</sup> EzSimva GH 10/10 [GQ]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/10 [CR]

<sup>a</sup> Vytorin [AL]<sup>a</sup> Zeklen 10/10 mg [AF]<sup>a</sup> Zimybe 10/10 [MQ]**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

13442L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*30.99	31.60	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/20 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/20 [WG] <sup>a</sup> EzSimva GH 10/20 [GQ]  <sup>a</sup> Vytorin [AL] <sup>a</sup> Zimybe 10/20 [MQ]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/20 [CR] <sup>a</sup> Zeklen 10/20 mg [AF]

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

13535J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*32.17	31.60	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/40 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/40 [WG] <sup>a</sup> EzSimva GH 10/40 [GQ]  <sup>a</sup> Zeklen 10/40 mg [AF] <sup>a</sup> Vytorin [AL]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/40 [CR] <sup>a</sup> Zimybe 10/40 [MQ]
			<sup>B</sup> 4.00	*36.17	31.60		

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

13595M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*33.83	31.60	<sup>a</sup> APO-Ezetimibe/Simvastatin 10/80 [TX] <sup>a</sup> EZETIMIBE/SIMVASTATIN-WGR 10/80 [WG] <sup>a</sup> EzSimva GH 10/80 [GQ]  <sup>a</sup> Zeklen 10/80 mg [AF] <sup>a</sup> Vytorin [AL]	<sup>a</sup> EZETIMIBE/SIMVASTATIN SANDOZ [SZ] <sup>a</sup> EZETORIN [RW]  <sup>a</sup> Pharmacor Ezetimibe Simvastatin 10/80 [CR] <sup>a</sup> Zimybe 10/80 [MQ]
			<sup>B</sup> 4.00	*37.83	31.60		

*Lipid modifying agents in combination with other drugs***■ AMLODIPINE + ATORVASTATIN****amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

9053L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.10	18.55	<sup>a</sup> Cadivast 10/10 [AF]
			<sup>B</sup> 5.00	22.10	18.55	<sup>a</sup> Caduet 10/10 [AS]

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

9054M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.30	18.75	<sup>a</sup> Cadivast 10/20 [AF]
			<sup>B</sup> 5.00	22.30	18.75	<sup>a</sup> Caduet 10/20 [AS]

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

9055N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.21	19.66	<sup>a</sup> Cadivast 10/40 [AF]
			<sup>B</sup> 5.00	23.21	19.66	<sup>a</sup> Caduet 10/40 [AS]

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

9056P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.58	21.03	<sup>a</sup> Cadivast 10/80 [AF]
			<sup>B</sup> 5.00	24.58	21.03	<sup>a</sup> Caduet 10/80 [AS]

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

9049G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.42	17.87	Cadivast 5/10 [AF]

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

9050H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.15	18.60	Cadivast 5/20 [AF]

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

9051J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.52	18.97	<sup>a</sup> Cadivast 5/40 [AF]
			<sup>B</sup> 5.00	22.52	18.97	<sup>a</sup> Caduet 5/40 [AS]

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

9052K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.89	20.34	<sup>a</sup> Cadivast 5/80 [AF]
			<sup>B</sup> 5.00	23.89	20.34	<sup>a</sup> Caduet 5/80 [AS]

**■ AMLODIPINE + ATORVASTATIN****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

13479K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.75	22.20	<sup>a</sup> Cadivast 10/10 [AF]
			<sup>B</sup> 10.00	*30.75	22.20	<sup>a</sup> Caduet 10/10 [AS]

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

13384K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.15	22.60	<sup>a</sup> Cadivast 10/20 [AF]
			<sup>B</sup> 10.00	*31.15	22.60	<sup>a</sup> Caduet 10/20 [AS]

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

13536K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*22.97	24.42	<sup>a</sup> Cadivast 10/40 [AF]
			<sup>B</sup> 10.00	*32.97	24.42	<sup>a</sup> Caduet 10/40 [AS]

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

13963X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.71	27.16	<sup>a</sup> Cadivast 10/80 [AF]
			<sup>B</sup> 10.00	*35.71	27.16	<sup>a</sup> Caduet 10/80 [AS]

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

13596N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*19.39	20.84	Cadivast 5/10 [AF]

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

13567C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.85	22.30	Cadivast 5/20 [AF]

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

13415C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.59	23.04	<sup>a</sup> Cadivast 5/40 [AF]
			<sup>B</sup> 10.00	*31.59	23.04	<sup>a</sup> Caduet 5/40 [AS]

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

13597P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.33	25.78	<sup>a</sup> Cadivast 5/80 [AF]
			<sup>B</sup> 10.00	*34.33	25.78	<sup>a</sup> Caduet 5/80 [AS]

**■ DERMATOLOGICALS****■ ANTIFUNGALS FOR DERMATOLOGICAL USE****ANTIFUNGALS FOR TOPICAL USE**

*Imidazole and triazole derivatives*

**■ MICONAZOLE****Authority required (STREAMLINED)**

**6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**miconazole 2% solution, 30 mL**

9031H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	21.93	23.38	Daktarin Tincture [JT]

**miconazole nitrate 2% cream, 30 g**

9027D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	19.03	20.48	Daktarin [JT]

**miconazole nitrate 2% cream, 70 g**

9028E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	20.24	21.69	Daktarin [JT]

**miconazole nitrate 2% powder, 30 g**

9029F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	19.53	20.98	Daktarin [JT]

*Other antifungals for topical use***■ TERBINAFINE****Authority required (STREAMLINED)****6434**

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)****6412**

Fungal or yeast infection

**Clinical criteria:**

- The condition must be fungal; OR
- The condition must be due to yeast.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine hydrochloride 1% cream, 15 g**

9160D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*40.37	31.60	Lamisil [NP]

**ANTIFUNGALS FOR SYSTEMIC USE***Antifungals for systemic use***■ GRISEOFULVIN****griseofulvin 125 mg tablet, 100**

1460W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	24.14	25.59	Grisovin [AS]

**griseofulvin 500 mg tablet, 28**

2982Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	24.77	26.22	Grisovin 500 [AS]

**■ TERBINAFINE****Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required**

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

2285G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	26.23	27.68	<sup>a</sup> APO-Terbinafine [TX] <sup>a</sup> Tamsil [RW] <sup>a</sup> Terbinafine Sandoz [SZ] <sup>a</sup> Tinasil [AF]	<sup>a</sup> NOUMED TERBINAFINE [VO] <sup>a</sup> Terbinafine-DRLA [RZ] <sup>a</sup> TERBINAFINE-WGR [WG]
			<sup>b</sup> 7.25	33.48	27.68	<sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]	

**■ TERBINAFINE****Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

**terbinafine 250 mg tablet, 42**

2804N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	26.23	27.68	<sup>a</sup> APO-Terbinafine [TX]	<sup>a</sup> NOUMED TERBINAFINE [VO]
						<sup>a</sup> Tamsil [RW]	<sup>a</sup> Terbinafine-DRLA [RZ]
						<sup>a</sup> Terbinafine Sandoz [SZ]	<sup>a</sup> TERBINAFINE-WGR [WG]
						<sup>a</sup> Tinasil [AF]	
			<sup>b</sup> 7.25	33.48	27.68	<sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]	

## ■ ANTIPSORIATICS

### ANTIPSORIATICS FOR TOPICAL USE

*Other antipsoriatics for topical use*

## ■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

11091R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	85.70	31.60	<sup>a</sup> Enstilar [LO]	<sup>a</sup> Klarvanta [LG]

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

9494Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	39.08	31.60	<sup>a</sup> Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	<sup>a</sup> Daivobet [LO]

## ■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

13520N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	1	..	*160.17	31.60	<sup>a</sup> Enstilar [LO]	<sup>a</sup> Klarvanta [LG]

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

13577N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	1	..	*64.71	31.60	<sup>a</sup> Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	<sup>a</sup> Daivobet [LO]

### ANTIPSORIATICS FOR SYSTEMIC USE

*Retinoids for treatment of psoriasis*

## ■ ACITRETIN

**Caution** This drug is a potent teratogen - pregnancy should be avoided during therapy and for at least three years after cessation of therapy.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)****5789**

Severe intractable psoriasis

**Authority required (STREAMLINED)****5727**

Severe disorders of keratinisation

**acitretin 10 mg capsule, 100**

2019G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	109.71	31.60	<sup>a</sup> Neotigason [TB]	<sup>a</sup> ZETIN [RW]

**acitretin 25 mg capsule, 100**

2020H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	213.99	31.60	<sup>a</sup> Neotigason [TB]	<sup>a</sup> ZETIN [RW]

## ■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

## CHEMOTHERAPEUTICS FOR TOPICAL USE

*Sulfonamides*

## ■ SILVER SULFADIAZINE

**Restricted benefit**

Infection

Treatment Phase: Prevention and treatment

**Clinical criteria:**

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

**Restricted benefit**

Stasis ulcers

**silver sulfadiazine 1% cream, 50 g**

9479X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.46	21.91	Flamazine [SN]

NP

## ■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

## CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

## ■ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

2881P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.37	17.82	<sup>a</sup> Cortic-DS 1% [LN]
			<sup>B</sup> 2.19	18.56	17.82	<sup>a</sup> Sigmacort [AS]

NP

**hydrocortisone acetate 1% ointment, 50 g**

2882Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.37	17.82	<sup>a</sup> Cortic-DS 1% [LN]
			<sup>B</sup> 2.19	18.56	17.82	<sup>a</sup> Sigmacort [AS]

NP

## ■ HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

5113D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.37	17.82	<sup>a</sup> Cortic-DS 1% [LN]
			<sup>B</sup> 2.19	18.56	17.82	<sup>a</sup> Sigmacort [AS]

DP

**hydrocortisone acetate 1% ointment, 50 g**

5114E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.37	17.82	<sup>a</sup> Cortic-DS 1% [LN]
			<sup>B</sup> 2.19	18.56	17.82	<sup>a</sup> Sigmacort [AS]

DP

*Corticosteroids, moderately potent (group II)*■ **TRIAMCINOLONE****Restricted benefit**

Corticosteroid-responsive dermatoses

**triamcinolone acetate 0.02% cream, 100 g**

2117K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*20.99	22.44	<sup>a</sup> Tricortone [LN]
			<sup>B</sup> 3.28	*24.27	22.44	<sup>a</sup> Aristocort 0.02% [AS]

**triamcinolone acetate 0.02% ointment, 100 g**

2118L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*20.99	22.44	<sup>a</sup> Tricortone [LN]
			<sup>B</sup> 3.28	*24.27	22.44	<sup>a</sup> Aristocort 0.02% [AS]

*Corticosteroids, potent (group III)*■ **BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as dipropionate) 0.05% cream, 15 g**

1115Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.38	18.83	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 2.45	19.83	18.83	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

1119X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.38	18.83	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 2.45	19.83	18.83	<sup>a</sup> Diprosone [AF]

■ **BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10824Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.31	22.76	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 4.90	*26.21	22.76	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10795E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.31	22.76	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 4.90	*26.21	22.76	<sup>a</sup> Diprosone [AF]

■ **BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10800K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*29.15	30.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 9.80	*38.95	30.60	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10820L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*29.15	30.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 9.80	*38.95	30.60	<sup>a</sup> Diprosone [AF]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10813D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*36.99	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 14.70	*51.69	31.60	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10821M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*36.99	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 14.70	*51.69	31.60	<sup>a</sup> Diprosone [AF]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10801L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*44.83	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 19.60	*64.43	31.60	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10816G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*44.83	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 19.60	*64.43	31.60	<sup>a</sup> Diprosone [AF]

**■ BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6231**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

10802M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*52.67	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 24.50	*77.17	31.60	<sup>a</sup> Diprosone [AF]

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

10823P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*52.67	31.60	<sup>a</sup> Eleuphrat [AL]
			<sup>B</sup> 24.50	*77.17	31.60	<sup>a</sup> Diprosone [AF]

**■ BETAMETHASONE VALERATE****Restricted benefit**

Corticosteroid-responsive dermatoses



**betamethasone (as valerate) 0.02% cream, 100 g**

2812B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*24.07	25.52	<sup>a</sup> Antroquoril [AL]
						<sup>b</sup> Cortival 1/5 [LN]
						<sup>b</sup> Betnovate 1/5 [AS]
						<sup>a</sup> Celestone-M [AF]

**■ BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.05% cream, 15 g**

2813C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.15	17.60	<sup>a</sup> Cortival 1/2 [LN]
						<sup>a</sup> Betnovate 1/2 [AS]

**■ BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10799J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*18.85	20.30	<sup>a</sup> Cortival 1/2 [LN]
						<sup>a</sup> Betnovate 1/2 [AS]

**■ BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10794D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*24.23	25.68	<sup>a</sup> Cortival 1/2 [LN]
						<sup>a</sup> Betnovate 1/2 [AS]

**■ BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10808W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*29.61	31.06	<sup>a</sup> Cortival 1/2 [LN]
						<sup>a</sup> Betnovate 1/2 [AS]

■ **BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10807T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*34.99	31.60	<sup>a</sup> Cortival 1/2 [LN]
			<sup>B</sup> 20.48	*55.47	31.60	<sup>a</sup> Betnovate 1/2 [AS]

■ **BETAMETHASONE VALERATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6231**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

10810Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*40.37	31.60	<sup>a</sup> Cortival 1/2 [LN]
			<sup>B</sup> 25.60	*65.97	31.60	<sup>a</sup> Betnovate 1/2 [AS]

■ **METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Corticosteroid-responsive dermatoses

**methylprednisolone aceponate 0.1% ointment, 15 g**

8055Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.78	20.23	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
			<sup>B</sup> 3.94	22.72	20.23	<sup>a</sup> Advantan [LO]	

**methylprednisolone aceponate 0.1% ointment, 15 g**

8128T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.78	20.23	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
			<sup>B</sup> 3.94	22.72	20.23	<sup>a</sup> Tanilone (Fatty) [AS]	<sup>a</sup> Advantan (Fatty) [LO]

**methylprednisolone aceponate 0.1% cream, 15 g**

8054X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.78	20.23	<sup>a</sup> Supriad Cream [XT]
			<sup>B</sup> 3.94	22.72	20.23	<sup>a</sup> Advantan [LO]

■ **METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Eczema

**methylprednisolone aceponate 0.1% lotion, 20 g**

8618N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.43	20.88	Advantan [LO]

■ **METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

10846W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.11	25.56	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
			<sup>B</sup> 7.88	*31.99	25.56	<sup>a</sup> Advantan [LO]	

**methylprednisolone aceponate 0.1% ointment, 15 g**

10848Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.11	25.56	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
						<sup>a</sup> Tanilone (Fatty) [AS]	
			<sup>B</sup> 7.88	*31.99	25.56	<sup>a</sup> Advantan (Fatty) [LO]	

**methylprednisolone aceponate 0.1% cream, 15 g**

10842P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.11	25.56	<sup>a</sup> Supriad Cream [XT]	
			<sup>B</sup> 7.88	*31.99	25.56	<sup>a</sup> Advantan [LO]	

**methylprednisolone aceponate 0.1% lotion, 20 g**

10856J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.41	26.86	Advantan [LO]	

■ **METHYLPREDNISOLONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

10836H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*34.75	31.60	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
			<sup>B</sup> 15.76	*50.51	31.60	<sup>a</sup> Advantan [LO]	

**methylprednisolone aceponate 0.1% ointment, 15 g**

10840M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*34.75	31.60	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
						<sup>a</sup> Tanilone (Fatty) [AS]	
			<sup>B</sup> 15.76	*50.51	31.60	<sup>a</sup> Advantan (Fatty) [LO]	

**methylprednisolone aceponate 0.1% cream, 15 g**

10855H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*34.75	31.60	<sup>a</sup> Supriad Cream [XT]	
			<sup>B</sup> 15.76	*50.51	31.60	<sup>a</sup> Advantan [LO]	

**methylprednisolone aceponate 0.1% lotion, 20 g**

10838K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*31.38	31.60	Advantan [LO]	

■ **METHYLPREDNISOLONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6231**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

10843Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*66.67	31.60	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
						<sup>a</sup> Tanilone (Fatty) [AS]	
			<sup>B</sup> 39.40	*106.07	31.60	<sup>a</sup> Advantan (Fatty) [LO]	

**methylprednisolone aceponate 0.1% ointment, 15 g**

10845T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*66.67	31.60	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
						<sup>a</sup> Advantan [LO]	
			<sup>B</sup> 39.40	*106.07	31.60		

**methylprednisolone aceponate 0.1% cream, 15 g**

10833E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*66.67	31.60	<sup>a</sup> Supriad Cream [XT]	
						<sup>a</sup> Advantan [LO]	
			<sup>B</sup> 39.40	*106.07	31.60		

**methylprednisolone aceponate 0.1% lotion, 20 g**

10830B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	5	..	*43.32	31.60	Advantan [LO]	

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

10844R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*45.39	31.60	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
						<sup>a</sup> Tanilone (Fatty) [AS]	
			<sup>B</sup> 23.64	*69.03	31.60	<sup>a</sup> Advantan (Fatty) [LO]	

**methylprednisolone aceponate 0.1% ointment, 15 g**

10853F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*45.39	31.60	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
						<sup>a</sup> Advantan [LO]	
			<sup>B</sup> 23.64	*69.03	31.60		

**methylprednisolone aceponate 0.1% cream, 15 g**

10835G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*45.39	31.60	<sup>a</sup> Supriad Cream [XT]	
						<sup>a</sup> Advantan [LO]	
			<sup>B</sup> 23.64	*69.03	31.60		

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

10834F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*56.03	31.60	<sup>a</sup> Metvant [NB]	<sup>a</sup> Supriad Ointment [XT]
						<sup>a</sup> Advantan [LO]	
			<sup>B</sup> 31.52	*87.55	31.60		

**methylprednisolone aceponate 0.1% ointment, 15 g**

10839L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*56.03	31.60	<sup>a</sup> Metvant (Fatty) [NB]	<sup>a</sup> Supriad Fatty Ointment [XT]
						<sup>a</sup> Tanilone (Fatty) [AS]	
			<sup>B</sup> 31.52	*87.55	31.60	<sup>a</sup> Advantan (Fatty) [LO]	

**methylprednisolone aceponate 0.1% cream, 15 g**

10851D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*56.03	31.60	<sup>a</sup> Supriad Cream [XT]
			<sup>B</sup> 31.52	*87.55	31.60	<sup>a</sup> Advantan [LO]

**■ METHYLPREDNISOLONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

10852E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*37.35	31.60	Advantan [LO]

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Corticosteroid-responsive dermatoses

**mometasone furoate 0.1% cream, 15 g**

1913Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.22	18.67	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 3.53	20.75	18.67	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% lotion, 30 mL**

8043H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.69	20.14	<sup>a</sup> Novasone [AF]	<sup>a</sup> Zatamil [EO]
			<sup>B</sup> 4.50	23.19	20.14	<sup>a</sup> Elocon [AL]	

**mometasone furoate 0.1% ointment, 15 g**

1915T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.22	18.67	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 3.53	20.75	18.67	<sup>a</sup> Elocon [AL]	

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6232**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10827W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 7.06	*28.05	22.44	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% lotion, 30 mL**

10819K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.93	25.38	<sup>a</sup> Novasone [AF]	<sup>a</sup> Zatamil [EO]
			<sup>B</sup> 9.00	*32.93	25.38	<sup>a</sup> Elocon [AL]	

**mometasone furoate 0.1% ointment, 15 g**

10812C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 7.06	*28.05	22.44	<sup>a</sup> Elocon [AL]	

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6246**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10809X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*28.51	29.96	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 14.12	*42.63	29.96	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% lotion, 30 mL**

10826T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*29.16	30.61	<sup>a</sup> Novasone [AF]	<sup>a</sup> Zatamil [EO]
			<sup>B</sup> 13.50	*42.66	30.61	<sup>a</sup> Elocon [AL]	

**mometasone furoate 0.1% ointment, 15 g**

10814E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*28.51	29.96	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 14.12	*42.63	29.96	<sup>a</sup> Elocon [AL]	

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10815F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*36.03	31.60	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 21.18	*57.21	31.60	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% ointment, 15 g**

10828X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*36.03	31.60	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
						<sup>a</sup> Zatamil [EO]	
			<sup>B</sup> 21.18	*57.21	31.60	<sup>a</sup> Elocon [AL]	

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10818J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*43.55	31.60	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 28.24	*71.79	31.60	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% ointment, 15 g**

10793C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*43.55	31.60	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 28.24	*71.79	31.60	<sup>a</sup> Zatamil [EO]	<sup>a</sup> Elocon [AL]

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6231**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

10792B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*51.07	31.60	<sup>a</sup> Momasone Alcohol Free [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 35.30	*86.37	31.60	<sup>a</sup> Elocon Alcohol Free [AL]	

**mometasone furoate 0.1% lotion, 30 mL**

10804P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	5	..	*39.62	31.60	<sup>a</sup> Novasone [AF]	<sup>a</sup> Zatamil [EO]
			<sup>B</sup> 22.50	*62.12	31.60	<sup>a</sup> Elocon [AL]	

**mometasone furoate 0.1% ointment, 15 g**

10791Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*51.07	31.60	<sup>a</sup> Momasone [AS]	<sup>a</sup> Novasone [AF]
			<sup>B</sup> 35.30	*86.37	31.60	<sup>a</sup> Zatamil [EO]	<sup>a</sup> Elocon [AL]

**■ MOMETASONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****6263**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**Authority required (STREAMLINED)****6218**

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

10805Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*34.39	31.60	<sup>a</sup> Novasone [AF]	<sup>a</sup> Zatamil [EO]
			<sup>B</sup> 18.00	*52.39	31.60	<sup>a</sup> Elocon [AL]	

*Corticosteroids, very potent (group IV)***■ CLOBETASOL****Authority required (STREAMLINED)****5461**

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be aged 18 years or older.

**clobetasol propionate 0.05% shampoo, 125 mL**

10080M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	47.50	31.60	Clobex [GA]

## ANTI-ACNE PREPARATIONS

### ANTI-ACNE PREPARATIONS FOR TOPICAL USE

#### Retinoids for topical use in acne

#### ADAPALENE + BENZOYL PEROXIDE

##### Restricted benefit

Severe acne vulgaris

Treatment Phase: Acute treatment

##### Clinical criteria:

- The treatment must in combination with an oral antibiotic.

##### adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

8954G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	36.15	31.60	Epiduo [GA]

#### ADAPALENE + BENZOYL PEROXIDE

##### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

##### Restricted benefit

Severe acne vulgaris

##### Clinical criteria:

- The treatment must be maintenance therapy.

##### adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

8955H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	36.15	31.60	Epiduo [GA]

NP

#### ADAPALENE + BENZOYL PEROXIDE

##### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

##### Restricted benefit

Severe acne vulgaris

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be maintenance therapy.

##### adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

13363H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	3	..	*58.85	31.60	Epiduo [GA]

NP

### ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

#### Retinoids for treatment of acne

#### ISOTRETINOIN

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

##### Authority required (STREAMLINED)

**5224**

Severe cystic acne

##### Clinical criteria:

- The condition must be unresponsive to other therapy.

##### isotretinoin 30 mg capsule, 60

11921K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	63.42	31.60	Oratane [OU]

##### isotretinoin 10 mg capsule, 60

2591J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	33.20	31.60	<sup>a</sup> APO-Isotretinoin [TX]	<sup>a</sup> Dermatane [ZS]
						<sup>a</sup> Isotretinoin GX [SZ]	<sup>a</sup> Isotretinoin Lupin [GQ]
						<sup>a</sup> ISOTRETINOIN-WGR [WG]	<sup>a</sup> Oratane [RF]



**isotretinoin 40 mg capsule, 30**

2549E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	46.77	31.60	<sup>a</sup> Dermatane [ZS]	<sup>a</sup> Oratane [RF]

**isotretinoin 5 mg capsule, 60**

11716P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	25.30	26.75	Oratane [OU]	

**■ ISOTRETINOIN**

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

**5224**

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**isotretinoin 20 mg capsule, 30**

11621P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*44.25	31.60	<sup>a</sup> Roaccutane [PB]	

**isotretinoin 20 mg capsule, 60**

2592K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	44.23	31.60	<sup>a</sup> APO-Isotretinoin [TX] <sup>a</sup> Isotretinoin GX [SZ] <sup>a</sup> ISOTRETINOIN-WGR [WG] <sup>a</sup> Pharmacor Isotretinoin [CR]	<sup>a</sup> Dermatane [ZS] <sup>a</sup> Isotretinoin Lupin [GQ] <sup>a</sup> Oratane [RF]

**■ OTHER DERMATOLOGICAL PREPARATIONS****OTHER DERMATOLOGICAL PREPARATIONS**

*Agents for dermatitis, excluding corticosteroids*

**■ DUPILUMAB**

**Note** Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here:  
<https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf>

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:  
<https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

- (a) current scores; or
  - (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.
- The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Note** Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

#### **Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

#### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

#### **Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

#### **Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

#### **Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

#### **Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

#### **Population criteria:**

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

- (i) erythema,
- (ii) oedema/papulation,
- (iii) excoriation,
- (iv) lichenification

Acceptable scores can be:

- (a) current scores; or
- (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

#### **Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

#### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

#### **Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

#### **dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12292Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1755.66	31.60	Dupixent [SW]

#### **dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12291X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1755.66	31.60	Dupixent [SW]

### ■ PIMECROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**5482**

Atopic dermatitis

#### **Population criteria:**

- Patient must be at least 3 months of age.

#### **Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

#### **Authority required (STREAMLINED)**

**5472**

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

#### **Population criteria:**

- Patient must be at least 3 months of age.

#### **Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**

- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
  - Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.
- Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
- (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
  - (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
  - (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
  - (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

### pimecrolimus 1% cream, 15 g

8802G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	34.03	31.60	Elidel [GO]

### Other dermatologicals

## ■ DAPSONE

### dapsone 100 mg tablet, 100

1272Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	401.14	31.60	<sup>a</sup> DAPSOMED [DZ]	<sup>a</sup> Link Medical Products Pty Ltd [LM]

### dapsone 25 mg tablet, 100

8801F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	328.45	31.60	Link Medical Products Pty Ltd [LM]

## ■ IMIQUIMOD

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Treatment of recurrent (previously treated) lesions will not be authorised.

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

### Authority required

Superficial basal cell carcinoma

### Clinical criteria:

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

### imiquimod 5% cream, 2 x 2 g

2637T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	<sup>B</sup> 8.35	97.34	31.60	<sup>a</sup> Aldara Pump [IL]

### imiquimod 5% cream, 12 x 250 mg sachets

2546B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	88.99	31.60	<sup>a</sup> Aldiq [AF]	<sup>a</sup> APO-Imiquimod [TX]
			<sup>B</sup> 3.30	92.29	31.60	<sup>a</sup> Aldara [IL]	

## ■ GENITO URINARY SYSTEM AND SEX HORMONES

## ■ OTHER GYNECOLOGICALS

### CONTRACEPTIVES FOR TOPICAL USE

#### Intrauterine contraceptives

## ■ LEVONORGESTREL

### Restricted benefit

Contraception

**levonorgestrel 19.5 mg intrauterine drug delivery system, 1 system**

11909T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	171.79	31.60	Kyleena [SY]

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

14705Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	191.73	31.60	Mirena [BN]

▪ **LEVONORGESTREL**

**Restricted benefit**

Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are ineffective.

**Restricted benefit**

Idiopathic menorrhagia

**Clinical criteria:**

- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

8633J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	191.73	31.60	Mirena [BN]

**OTHER GYNECOLOGICALS**

*Prolactine inhibitors*

▪ **BROMOCRIPTINE**

**Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

1444B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	23.09	24.54	Parlodel [SZ]

▪ **BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*32.73	31.60	Parlodel [SZ]

▪ **BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

13979R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*51.99	31.60	Parlodel [SZ]

**■ CABERGOLINE****Restricted benefit**

Prevention of the onset of lactation

**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**cabergoline 500 microgram tablet, 2**

8115D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	26.82	28.27	Dostinex [PF]

NP MW

**■ CABERGOLINE****Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

8114C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.92	31.60	<sup>a</sup> Dostamine [NB]	<sup>a</sup> Dostinex [PF]

**■ CABERGOLINE****Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

13901P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*120.73	31.60	<sup>a</sup> Dostamine [NB]	<sup>a</sup> Dostinex [PF]

**■ QUINAGOLIDE****Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**quinagolide 75 microgram tablet, 30**

8822H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	75.35	31.60	Norprolac [FP]

**■ QUINAGOLIDE****Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**quinagolide 75 microgram tablet, 30**

13982X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*138.43	31.60	Norprolac [FP]

## SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

### HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

#### Progestogens and estrogens, fixed combinations

#### ■ DROSPIRENONE + ETHINYLESTRADIOL

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 28**

14710F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*62.34	31.60	Yaz [BN]

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 3 x 28**

14709E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	62.33	31.60	Yaz [BN]

**drospirenone 3 mg + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 28**

14711G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*62.34	31.60	Yasmin [BN]

**drospirenone 3 mg + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 3 x 28**

14725B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	62.33	31.60	Yasmin [BN]

#### ■ LEVONORGESTREL + ETHINYLESTRADIOL

**levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1456P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	23.33	24.78	Microgynon 50 ED [BN]

**levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

1394J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	17.87	19.32	<sup>a</sup> Eleanor 150/30 ED [XT] <sup>a</sup> Femme-Tab ED 30/150 [AE] <sup>a</sup> LEVETH 150/30 ED [WG]	<sup>a</sup> Evelyn 150/30 ED [GQ] <sup>a</sup> Lenest 30 ED [AF] <sup>a</sup> Micronelle 30 ED [TX]
			<sup>B</sup> 5.66	23.53	19.32	<sup>a</sup> Levlen ED [SY]	

**levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2416E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	19.57	21.02	Femme-Tab ED 20/100 [AE]

#### ■ NORETHISTERONE + ETHINYLESTRADIOL

**norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2774B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	24.81	26.26	Norimin 28 Day [FZ]

#### ■ NORETHISTERONE + ETHINYLESTRADIOL

**Note** Pharmaceutical benefits that have the form norethisterone 1 mg + ethinylestradiol 35 microgram tablet in a 4 pack of 28 tablets can be substituted for a 3 pack of 28 tablets in the case of a shortage.



**norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

2775C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	24.81	26.26	Norimin-1 28 Day [FZ]

*Progestogens and estrogens, sequential preparations***LEVONORGESTREL + ETHINYLESTRADIOL**

**levonorgestrel 50 microgram + ethinylestradiol 30 microgram tablet [6] (&) levonorgestrel 75 microgram + ethinylestradiol 40 microgram tablet [5] (&) levonorgestrel 125 microgram + ethinylestradiol 30 microgram tablet [10] (&) inert substance tablet [7], 4 x 28**

1392G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	21.18	22.63	Trifeme 28 [FZ]
			<sup>B</sup> 13.56	34.74	22.63	<sup>a</sup> Logynon ED [SY]
						<sup>a</sup> Triquilar ED [BN]

*Progestogens***ETONOGESTREL**

**etonogestrel 68 mg implant, 1**

8487Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	171.79	31.60	Implanon NXT [OQ]

**LEVONORGESTREL**

**levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]**

2913H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	2	..	21.16	22.61	Microlut 28 [BN]

**MEDROXYPROGESTERONE**

**medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe**

14160G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	27.59	29.04	Depo-Provera [PF]

**NORETHISTERONE**

**norethisterone 350 microgram tablet, 4 x 28**

1967M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	2	..	24.81	26.26	Noriday 28 Day [PF]

**ANDROGENS***3-oxoandrosten (4) derivatives***TESTOSTERONE****Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

- (i) testosterone level of less than 6 nmol per litre; OR
- (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

#### **Authority required**

Micropenis

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

#### **Authority required**

Pubertal induction

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

#### **Authority required**

Constitutional delay of growth or puberty

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

#### **testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets**

8830R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	78.96	31.60	Testogel [HB]

#### **testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations**

10380H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	4	..	78.96	31.60	Testogel [HB]

#### **testosterone 2% (23 mg/actuation) gel, 56 actuations**

11740X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	84.41	31.60	Testavan [IX]

### ■ TESTOSTERONE

#### **Authority required**

Androgen deficiency

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

#### **Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

#### **Authority required**

Androgen deficiency

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

#### **Population criteria:**

- Patient must be aged 40 years or older.

#### **Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

- (i) testosterone level of less than 6 nmol per litre; OR
- (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets**

13983Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*146.01	31.60	Testogel [HB]

**testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations**

13924W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	4	..	*146.01	31.60	Testogel [HB]

**testosterone 2% (23 mg/actuation) gel, 56 actuations**

14025E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*157.45	31.60	Testavan [IX]

■ **TESTOSTERONE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

## Clinical criteria:

- The treatment must be applied to the scrotum, where possible.
- The name of the specialist must be included in the authority application.

## Authority required

Androgen deficiency

## Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

## Population criteria:

- Patient must be aged 40 years or older.

## Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

## Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

## Authority required

Micropenis

## Population criteria:

- Patient must be under 18 years of age.

## Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

## Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

## Authority required

Pubertal induction

## Population criteria:

- Patient must be under 18 years of age.

## Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

## Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

## Authority required

Constitutional delay of growth or puberty

## Population criteria:

- Patient must be under 18 years of age.

## Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

## Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

## testosterone 5% (50 mg/mL) cream, 50 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10378F	±1	1	..	107.54	31.60	AndroForte 5 [LX]

## TESTOSTERONE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

## Authority required

Androgen deficiency

## Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.
- The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.
- The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.
- The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.
- The name of the specialist must be included in the authority application.

**testosterone 5% (50 mg/mL) cream, 50 mL**

14563L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	1	..	*206.03	31.60	AndroForte 5 [LX]

**■ TESTOSTERONE UNDECANOATE**
**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

- (i) testosterone level of less than 6 nmol per litre; OR
- (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial**

10205D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	94.43	31.60	<sup>a</sup> Gonadron [RA] <sup>a</sup> REJUNON 1000 [JU]	<sup>a</sup> Reandron 1000 [AS] <sup>a</sup> Testosterone ADVZ 1000 [BZ]

**ESTROGENS**

*Natural and semisynthetic estrogens, plain*

■ **ESTRADIOL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 2 mg tablet, 56**

8274L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	19.66	21.11	Zumenon [XT]

**estradiol valerate 1 mg tablet, 56**

1663M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	16.59	18.04	Progynova [BN]

**estradiol valerate 2 mg tablet, 56**

1664N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.91	19.36	Progynova [BN]

**estradiol 10 microgram modified release pessary, 18**

10203B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	30.02	31.47	<sup>a</sup> Estro-Pess [AS]	<sup>a</sup> Vagifem Low [NO]

■ **ESTRADIOL**

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

8286D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	25.63	27.08	Sandrena [OX]

**estradiol 37.5 microgram/24 hours patch, 8**

8762E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	30.28	31.60	<sup>a</sup> Estradiol Transdermal System (Sandoz, USA) [HX]	<sup>a</sup> Estradot 37.5 [SZ]

**estradiol 75 microgram/24 hours patch, 8**

8764G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	31.58	31.60	Estradot 75 [SZ]

**estradiol 100 microgram/24 hours patch, 8**

8312L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	26.82	28.27	Estraderm MX 100 [JU]

**estradiol 100 microgram/24 hours patch, 8**

8765H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	30.88	31.60	<sup>a</sup> Estradiol Transdermal System (Sandoz, USA) [HX]	<sup>a</sup> Estradot 100 [SZ]

**estradiol 50 microgram/24 hours patch, 8**

8140K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	24.99	26.44	Estraderm MX 50 [JU]

**estradiol 50 microgram/24 hours patch, 8**

8763F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	30.13	31.58	Estradot 50 [SZ]

**estradiol 25 microgram/24 hours patch, 8**

8311K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	24.99	26.44	Estraderm MX 25 [JU]

**estradiol 25 microgram/24 hours patch, 8**

8761D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	30.98	31.60	Estradot 25 [SZ]

**estradiol 25 microgram/24 hours patch, 24**

14691F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	66.01	31.60	Estramon (Germany, Sandoz) [SZ]

**estradiol 0.06% (750 microgram/actuation) gel, 64 actuations**

14719Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	36.21	31.60	EstroGel [HB]

**estradiol 0.1% (1 mg/g) gel, 28 x 500 mg sachets**

14653F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.98	23.43	Sandrena [OX]

**estradiol 75 microgram/24 hours patch, 24**

14652E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	67.81	31.60	Estramon (Germany, Sandoz) [SZ]

**estradiol 100 microgram/24 hours patch, 24**

14715L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	65.71	31.60	Estramon (Germany, Sandoz) [SZ]

**estradiol 50 microgram/24 hours patch, 24**

14660N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	63.46	31.60	Estramon (Germany, Sandoz) [SZ]

**■ ESTRADIOL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 2 mg tablet, 56**

13931F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*25.87	27.32	Zumenon [XT]

**estradiol valerate 1 mg tablet, 56**

13872D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*19.73	21.18	Progynova [BN]

**estradiol valerate 2 mg tablet, 56**

13980T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*22.37	23.82	Progynova [BN]

**estradiol 10 microgram modified release pessary, 18**

13978Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*46.59	31.60	<sup>a</sup> Estro-Pess [AS]	<sup>a</sup> Vagifem Low [NO]

**■ ESTRADIOL**

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.



**estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14026F	±2	5	..	*37.81	31.60	Sandrena [OX]

**estradiol 0.06% (750 microgram/actuation) gel, 64 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14741W	2	5	..	*58.97	31.60	Estrogel [HB]

**estradiol 0.1% (1 mg/g) gel, 28 x 500 mg sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14642P	2	5	..	*30.51	31.60	Sandrena [OX]

▪ **ESTRIOL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estriol 500 microgram pessary, 15**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1771F	±1	2	..	26.27	27.72	Ovestin Ovula [AS]

**estriol 0.1% (1 mg/g) cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1781R	±1	1	..	24.78	26.23	Ovestin [AS]

▪ **ESTRIOL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estriol 500 microgram pessary, 15**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14059Y	±2	2	..	*39.09	31.60	Ovestin Ovula [AS]

**estriol 0.1% (1 mg/g) cream, 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13926Y	±2	1	..	*36.11	31.60	Ovestin [AS]

**PROGESTOGENS**

*Pregnen (4) derivatives*

▪ **MEDROXYPROGESTERONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**medroxyprogesterone acetate 10 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2321E	1	2	..	20.33	21.78	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 6.70	27.03	21.78	<sup>a</sup> Provera [PF]

**medroxyprogesterone acetate 5 mg tablet, 56**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2323G	1	2	..	18.94	20.39	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 4.58	23.52	20.39	<sup>a</sup> Provera [PF]

▪ **MEDROXYPROGESTERONE**

**Restricted benefit**

Endometriosis

**medroxyprogesterone acetate 10 mg tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2722G	1	2	..	36.36	31.60	<sup>a</sup> Ralovera [FZ]

<sup>B</sup>6.70      43.06      31.60      <sup>a</sup> Provera [PF]

## ■ MEDROXYPROGESTERONE

### Restricted benefit

Endometriosis

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### medroxyprogesterone acetate 10 mg tablet, 100

13928C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*59.27	31.60	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 13.40	*72.67	31.60	<sup>a</sup> Provera [PF]

## ■ MEDROXYPROGESTERONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### medroxyprogesterone acetate 10 mg tablet, 30

13849X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*27.21	28.66	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 13.40	*40.61	28.66	<sup>a</sup> Provera [PF]

### medroxyprogesterone acetate 5 mg tablet, 56

13956M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*24.43	25.88	<sup>a</sup> Ralovera [FZ]
			<sup>B</sup> 9.16	*33.59	25.88	<sup>a</sup> Provera [PF]

## ■ PROGESTERONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### progesterone 100 mg capsule, 30

14730G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	43.51	31.60	Prometrium [HB]

## ■ PROGESTERONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### progesterone 100 mg capsule, 30

14733K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*73.57	31.60	Prometrium [HB]

## ■ PROGESTERONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**11835**

Prevention of preterm birth

### Clinical criteria:

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 42**

12598C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	3	..	94.67	31.60	Utrogestan [HB]

**■ PROGESTERONE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****11673**

Prevention of preterm birth

**Clinical criteria:**

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 15**

12465C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	3	3	..	*128.34	31.60	Oripro [ON]

***Pregnadien derivatives*****■ DIENOGEST****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****16222**

Endometriosis

**dienogest 2 mg tablet, 28**

14667Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	57.70	31.60	Visanne [BN]

***Estren derivatives*****■ NORETHISTERONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**norethisterone 5 mg tablet, 30**

2993M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	35.67	31.60	Primolut N [BN]

**■ NORETHISTERONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**norethisterone 5 mg tablet, 30**

13873E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*57.89	31.60	Primolut N [BN]

**PROGESTOGENS AND ESTROGENS IN COMBINATION*****Progestogens and estrogens, fixed combinations*****■ ESTRADIOL + NORETHISTERONE ACETATE**

**Note** Pharmaceutical benefits that have the brand ESTALIS 140/50 (Canada) can be substituted for pharmaceutical benefits that have the brand Estalis continuous 50/140 in the case of a shortage.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

14728E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	176.63	31.60	<sup>a</sup> ESTALIS 140/50 (Canada) [DZ]

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

8427M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	36.48	31.60	<sup>a</sup> Estalis continuous 50/140 [SZ]

**■ ESTRADIOL + NORETHISTERONE ACETATE**

**Note** Pharmaceutical benefits that have the brand ESTALIS 250/50 (Canada) can be substituted for pharmaceutical benefits that have the brand Estalis continuous 50/250 in the case of a shortage

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

14739R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	176.63	31.60	<sup>a</sup> ESTALIS 250/50 (Canada) [DZ]

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

8428N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	34.73	31.60	<sup>a</sup> Estalis continuous 50/250 [SZ]

**■ ESTRADIOL + NORETHISTERONE ACETATE**

**Note** Pharmaceutical benefits that have the brand ESTALIS 140/50 (Canada) can be substituted for pharmaceutical benefits that have the brand Estalis continuous 50/140 in the case of a shortage.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

13902Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*59.51	31.60	<sup>a</sup> Estalis continuous 50/140 [SZ]

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

14727D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*344.79	31.60	<sup>a</sup> ESTALIS 140/50 (Canada) [DZ]

**■ ESTRADIOL + NORETHISTERONE ACETATE**

**Note** Pharmaceutical benefits that have the brand ESTALIS 250/50 (Canada) can be substituted for pharmaceutical benefits that have the brand Estalis continuous 50/250 in the case of a shortage

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

14336M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*56.01	31.60	<sup>a</sup> Estalis continuous 50/250 [SZ]

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

14731H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*344.79	31.60	<sup>a</sup> ESTALIS 250/50 (Canada) [DZ]

**■ PROGESTERONE (&) ESTRADIOL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14721T	±1	5	..	58.72	31.60	EstroGel Pro [HB]

**■ PROGESTERONE (&) ESTRADIOL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14720R	2	5	..	*103.99	31.60	EstroGel Pro [HB]

*Progestogens and estrogens, sequential preparations***■ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10146B	±1	5	..	24.19	25.64	Femoston 1/10 [XT]

**estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8244X	±1	5	..	24.19	25.64	Femoston 2/10 [XT]

**■ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14024D	±2	5	..	*34.93	31.60	Femoston 1/10 [XT]

**estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13930E	±2	5	..	*34.93	31.60	Femoston 2/10 [XT]

**■ ESTRADIOL (&) ESTRADIOL + NORETHISTERONE ACETATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8425K	±1	5	..	44.95	31.60	Estalis sequi 50/140 [SZ]

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8426L	±1	5	..	43.29	31.60	Estalis sequi 50/250 [SZ]

**■ ESTRADIOL (&) ESTRADIOL + NORETHISTERONE ACETATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

# **Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## **estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8**

13932G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*76.45	31.60	Estalis sequi 50/140 [SZ]

## **estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8**

13981W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*73.13	31.60	Estalis sequi 50/250 [SZ]

## **GONADOTROPINS AND OTHER OVULATION STIMULANTS**

### *Gonadotropins*

#### **■ CHORIOGONADOTROPIN ALFA**

**Note** Pharmaceutical benefits that have the form choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled syringe (Ovidrel USA) can be substituted for choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled pen in the case of a shortage.

# **Restricted benefit**

Infertility indications other than that of Assisted Reproductive Technology

## **Treatment criteria:**

- Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule, **AND**
- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing, **AND**
- Must be treated by an obstetrician/gynaecologist; OR
- Must be treated by a specialist in reproductive endocrinology/infertility; OR
- Must be treated by a urogynaecologist; OR
- Must be treated by an endocrinologist; OR
- Must be treated by a urologist.

The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.

## **choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device**

13300B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*304.63	31.60	<sup>a</sup> Ovidrel [SG]

## **choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL syringe**

14640M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*517.83	31.60	<sup>a</sup> Ovidrel (USA) [SG]

#### **■ FOLLITROPIN ALFA**

# **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand, Bemfola or Ovaleap, is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

# **Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

# **Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin alfa 300 units (21.84 microgram)/0.48 mL injection, 0.48 mL pen device**

8713N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*301.17	31.60	<sup>a</sup> Gonal-f Pen [SG]

**follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices**

10876K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*1035.12	31.60	Bemfola [FX]

**follitropin alfa 450 units (32.76 microgram)/0.72 mL injection, 0.72 mL pen device**

8714P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*447.51	31.60	<sup>a</sup> Gonal-f Pen [SG]

**follitropin alfa 900 units (65.52 microgram)/1.44 mL injection, 1.44 mL pen device**

8715Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*747.89	31.60	<sup>a</sup> Gonal-f Pen [SG]

**follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices**

10865W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*356.04	31.60	Bemfola [FX]

**follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices**

10877L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*703.59	31.60	Bemfola [FX]

**follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge**

12769C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*301.17	31.60	<sup>a</sup> Ovaleap [TT]

**follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge**

12808D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*447.51	31.60	<sup>a</sup> Ovaleap [TT]

**follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge**

12778M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*747.89	31.60	<sup>a</sup> Ovaleap [TT]

**■ FOLLITROPIN BETA**

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

8565T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*317.94	31.60	<sup>a</sup> Puregon 300 IU/0.36 mL [OQ]	<sup>a</sup> Recagon [OV]

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

8566W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*411.09	31.60	Puregon 600 IU/0.72 mL [OQ]

## GENITO URINARY SYSTEM AND SEX HORMONES

### follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

8871X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*607.01	31.60	<sup>a</sup> Puregon 900 IU/1.08 mL [OQ]	<sup>a</sup> Recagon [OV]

### ■ HUMAN CHORIONIC GONADOTROPHIN

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

#### Restricted benefit

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

#### Restricted benefit

Infertility

#### **Population criteria:**

- Patient must be male.

#### **Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism.

#### Restricted benefit

Infertility

#### **Population criteria:**

- Patient must be male.

#### **Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

#### Restricted benefit

Combined deficiency of human growth hormone and gonadotrophins

#### **Population criteria:**

- Patient must be male.

#### **Clinical criteria:**

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

#### Restricted benefit

Hypogonadism or delayed puberty

#### **Population criteria:**

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

#### **Clinical criteria:**

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

### human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

12905F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	97.42	31.60	Brevactid 1500 I.E [DZ]

### *Ovulation stimulants, synthetic*

### ■ CLOMIFENE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

#### Restricted benefit

Anovulatory infertility

#### Restricted benefit

Patients undergoing in-vitro fertilisation

### clomifene citrate 50 mg tablet, 10

1211R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.13	31.60	Clomid [SW]

## ANTIANDROGENS

### *Antiandrogens, plain*

### ■ CYPROTERONE

### cypoterone acetate 100 mg tablet, 50

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	61.27	31.60	<sup>a</sup> ANTERONE 100 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 1.21	62.48	31.60	<sup>a</sup> Androcur-100 [GH]	



**cyproterone acetate 50 mg tablet, 50**

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*74.87	31.60	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 1.96	*76.83	31.60	<sup>a</sup> Androcur [GH]	

**■ CYPROTERONE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**cyproterone acetate 100 mg tablet, 50**

14022B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*109.09	31.60	<sup>a</sup> ANTERONE 100 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 2.42	*111.51	31.60	<sup>a</sup> Androcur-100 [GH]	

**cyproterone acetate 50 mg tablet, 50**

14023C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*137.39	31.60	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 4.12	*141.51	31.60	<sup>a</sup> Androcur [GH]	

**■ CYPROTERONE**

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority required (STREAMLINED)****5532**

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

1269T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	25.74	27.19	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]

**■ CYPROTERONE**

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority required (STREAMLINED)****14868**

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

13925X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*38.03	31.60	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]

**OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM*****Progesterone receptor modulators*****■ MIFEPRISTONE (&) MISOPROSTOL**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14202**

Termination of an intra-uterine pregnancy

**Clinical criteria:**

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

## mifepristone 200 mg tablet [1] (&amp;) misoprostol 200 microgram tablet [4], 1 pack

10211K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	±1	..	..	390.73	31.60	MS-2 Step [XH]

## ■ UROLOGICALS

## UROLOGICALS

*Drugs for urinary frequency and incontinence*

## ■ OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

## oxybutynin hydrochloride 5 mg tablet, 100

8039D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.65	19.10	Ditropan [SW]

## ■ OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

## oxybutynin 3.9 mg/24 hours patch, 8

9454N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	32.28	31.60	Oxytrol [TT]

## ■ OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## oxybutynin hydrochloride 5 mg tablet, 100

13957N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.85	23.30	Ditropan [SW]

## ■ OXYBUTYNIN

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

## oxybutynin 3.9 mg/24 hours patch, 8

13984B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*51.11	31.60	Oxytrol [TT]

## ■ PROPANTHELINE

**Restricted benefit**

Detrusor overactivity

## propantheline bromide 15 mg tablet, 100

1953T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.49	25.94	Pro-Banthine [RW]

## ■ PROPANTHELINE

**Restricted benefit**

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propantheline bromide 15 mg tablet, 100**

13927B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*35.51	31.60	Pro-Banthine [RW]

*Other urologicals***■ BICARBONATE****sodium bicarbonate 840 mg capsule, 100**

9470K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	21.65	23.10	Sodibic [AS]

**■ BICARBONATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sodium bicarbonate 840 mg capsule, 100**

13933H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*29.85	31.30	Sodibic [AS]

**■ PHENOXYBENZAMINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*678.33	31.60	Amdipharm Mercury (Australia) Pty Limited [GH]

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	752.77	31.60	Dibenyline [GH]

**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY***Alpha-adrenoreceptor antagonists***■ DUTASTERIDE + TAMSULOSIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6189**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

5490Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.36	31.60	<sup>a</sup> Doubluts [GC]	<sup>a</sup> Dutasteride/Tamsulosin Lupin 500/400 [GQ]
						<sup>a</sup> Dutasteride/Tamsulosin Sandoz 500/400 [SZ]	<sup>a</sup> DUTATAM 500/400 [TN]
			<sup>B</sup> 3.50	34.86	31.60	<sup>a</sup> Duodart 500ug/400ug [GK]	

**■ DUTASTERIDE + TAMSULOSIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15004**

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Benign prostatic hyperplasia

## Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

## dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

13929D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*49.27	31.60	<sup>a</sup> Doubluts [GC]	<sup>a</sup> Dutasteride/Tamsulosin Lupin 500/400 [GQ]
						<sup>a</sup> Dutasteride/Tamsulosin Sandoz 500/400 [SZ]	<sup>a</sup> DUTATAM 500/400 [TN]
			<sup>B</sup> 7.00	*56.27	31.60	<sup>a</sup> Duodart 500ug/400ug [GK]	

## Testosterone-5-alpha reductase inhibitors

### ■ DUTASTERIDE

#### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**6202**

Benign prostatic hyperplasia

## Clinical criteria:

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

## dutasteride 500 microgram capsule, 30

5468T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	29.82	31.27	<sup>a</sup> APO-Dutasteride [TX]
			<sup>B</sup> 7.00	36.82	31.27	<sup>a</sup> Avodart [GK]

### ■ DUTASTERIDE

#### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**15018**

Benign prostatic hyperplasia

## Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

## dutasteride 500 microgram capsule, 30

13900N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*46.19	31.60	<sup>a</sup> APO-Dutasteride [TX]
			<sup>B</sup> 14.00	*60.19	31.60	<sup>a</sup> Avodart [GK]

## ■ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## ■ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

#### ACTH

### ■ TETRACOSACTIDE

#### Restricted benefit

Hypsarhythmia and/or infantile spasms

## tetracosactide 1 mg/mL modified release injection, 1 mL ampoule

2832C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*308.77	31.60	Synacthen Depot 1 mg/1 mL [IX]

#### Thyrotropin

■ **THYROTROPIN ALFA****Restricted benefit**

Ablation of thyroid remnant tissue

**Clinical criteria:**

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

**thyrotropin alfa 900 microgram injection, 2 vials**

2700D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1562.13	31.60	Thyrogen [GZ]

**POSTERIOR PITUITARY LOBE HORMONES***Vasopressin and analogues*■ **DESMOPRESSIN****Authority required (STREAMLINED)****5266**

Cranial diabetes insipidus

**desmopressin acetate 200 microgram tablet, 30**

8662X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*113.10	31.60	Minirin [FP]

■ **DESMOPRESSIN****Authority required (STREAMLINED)****15012**

Cranial diabetes insipidus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**desmopressin acetate 200 microgram tablet, 30**

13889B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*217.71	31.60	Minirin [FP]

■ **DESMOPRESSIN**

**Note** Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

**Authority required (STREAMLINED)****5266**

Cranial diabetes insipidus

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

8711L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*102.27	31.60	<sup>a</sup> Minirin Nasal Spray [FP]

**desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations**

12458Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*232.69	31.60	<sup>a</sup> Desmopressin Nasal Spray USP (Apotex) [DZ]

■ **DESMOPRESSIN**

**Note** Not to be used in preference to enuresis alarms.

**Authority required (STREAMLINED)****14945**

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****15025**

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No increase in the maximum quantity or number of units may be authorised.

**desmopressin 240 microgram sublingual wafer, 30**

13890C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*140.55	31.60	Minirin Melt [FP]

**■ DESMOPRESSIN**

**Note** Not to be used in preference to enuresis alarms.

**Authority required (STREAMLINED)****14972**

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.
- No more than twice the maximum quantity will be authorised.

**Authority required (STREAMLINED)****14842**

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No more than twice the maximum quantity will be authorised.

**desmopressin acetate 200 microgram tablet, 30**

13945Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*79.89	31.60	Minirin [FP]

**desmopressin 120 microgram sublingual wafer, 30**

14004C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*87.49	31.60	Minirin Melt [FP]

**■ DESMOPRESSIN**

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**Authority required (STREAMLINED)****5413**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Authority required (STREAMLINED)****5295**

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

### desmopressin acetate 200 microgram tablet, 30

8663Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	46.67	31.60	Minirin [FP]

## ■ DESMOPRESSIN

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

#### Authority required (STREAMLINED)

**5412**

Primary nocturnal enuresis

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

#### Authority required (STREAMLINED)

**5226**

Primary nocturnal enuresis

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

### desmopressin 120 microgram sublingual wafer, 30

9398P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	50.47	31.60	Minirin Melt [FP]

### desmopressin 240 microgram sublingual wafer, 30

8975J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	76.36	31.60	Minirin Melt [FP]

## ■ DESMOPRESSIN

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.

**Note** Not to be used in preference to enuresis alarms.

#### Authority required (STREAMLINED)

**5342**

Primary nocturnal enuresis

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

#### Authority required (STREAMLINED)

**5267**

Primary nocturnal enuresis

#### **Population criteria:**

- Patient must be 6 years of age or older.

#### **Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

### desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

8712M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	57.86	31.60	<sup>a</sup> Minirin Nasal Spray [FP]

### desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations

12459R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	120.58	31.60	<sup>a</sup> Desmopressin Nasal Spray USP (Apotex) [DZ]

## HYPOTHALAMIC HORMONES

## Gonadotropin-releasing hormones

## ■ NAFARELIN

**Restricted benefit**

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven.

**Restricted benefit**

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven, **AND**
  - The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
  - Patient must have had a recent bone density assessment.
- The date of the bone density assessment must be recorded in the patient's medical records.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

2962X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	124.30	31.60	Synarel [PF]

## ■ CORTICOSTEROIDS FOR SYSTEMIC USE

## CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

## Mineralocorticoids

## ■ FLUDROCORTISONE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**fludrocortisone acetate 100 microgram tablet, 100**

1433K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*35.15	31.60	<sup>a</sup> Florinef [AS]	<sup>a</sup> FLUDROCORTISONE MEDSURGE [DZ]

NP

## Glucocorticoids

## ■ ABIRATERONE (&amp;) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

13263C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	987.95	31.60	Yonsa Mpred [RA]

## ■ ABIRATERONE (&amp;) METHYLPREDNISOLONE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.



**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack**

14078Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	834.68	31.60	Yonsa Mpred [RA]

▪ **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

5034Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	29.62	31.07	Celestone Chronodose [OQ]

DP

▪ **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

**Restricted benefit**

Alopecia areata

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Uveitis

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

2694T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	29.62	31.07	Celestone Chronodose [OQ]

NP

▪ **CORTISONE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**cortisone acetate 25 mg tablet, 60**

1247P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	25.92	27.37	Cortate [AS]

NP

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## cortisone acetate 5 mg tablet, 50

1246N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	20.79	22.24	Cortate [AS]

## ■ CORTISONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## cortisone acetate 25 mg tablet, 60

13862N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*38.39	31.60	Cortate [AS]

## cortisone acetate 5 mg tablet, 50

13946B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*28.13	29.58	Cortate [AS]

## ■ DEXAMETHASONE

### dexamethasone 4 mg tablet, 30

2507Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	18.71	20.16	Dexmethsone [AS]

### dexamethasone 500 microgram tablet, 30

1292B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	16.17	17.62	Dexmethsone [AS]

## ■ DEXAMETHASONE

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### dexamethasone 500 microgram tablet, 30

14007F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*18.89	20.34	Dexmethsone [AS]

## ■ HYDROCORTISONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### hydrocortisone 20 mg tablet, 60

1500Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	34.10	31.60	<sup>a</sup> Hydrocortisone Viatris 20 [AL]
			<sup>B</sup> 3.00	37.10	31.60	<sup>a</sup> Hysone 20 [AF]

### hydrocortisone 4 mg tablet, 50

1499X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	27.92	29.37	<sup>a</sup> Hydrocortisone Viatris 4 [AL]
			<sup>B</sup> 3.00	30.92	29.37	<sup>a</sup> Hysone 4 [AF]

## ■ HYDROCORTISONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### hydrocortisone 20 mg tablet, 60

14476X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*54.75	31.60	<sup>a</sup> Hydrocortisone Viatris 20 [AL]
			<sup>B</sup> 6.00	*60.75	31.60	<sup>a</sup> Hysone 20 [AF]

**hydrocortisone 4 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13863P	2	4	..	*42.39	31.60	<sup>a</sup> Hydrocortisone Viatrix 4 [AL]
			<sup>B</sup> 6.00	*48.39	31.60	<sup>a</sup> Hysone 4 [AF]

**■ HYDROCORTISONE SODIUM SUCCINATE****hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1501B	2	..	..	*23.27	24.72	Solu-Cortef [PF]

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3096Y	1	..	..	22.22	23.67	Solu-Cortef [PF]

**■ HYDROCORTISONE SODIUM SUCCINATE****Restricted benefit**

For use in a hospital

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1510L	6	..	..	*42.87	31.60	Solu-Cortef [PF]

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5118J	6	..	..	*42.87	31.60	Solu-Cortef [PF]

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1511M	6	..	..	*66.03	31.60	Solu-Cortef [PF]

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5119K	6	..	..	*66.03	31.60	Solu-Cortef [PF]

**■ METHYLPREDNISOLONE****methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11739W	5	..	..	*43.07	31.60	Solu-Medrol [PF]

**methylprednisolone 1 g injection, 1 vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5264C	1	..	..	45.96	31.60	<sup>a</sup> Methylpred [AL]	<sup>a</sup> Solu-Medrol [PF]

**■ METHYLPREDNISOLONE****Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1928L	1	..	..	28.10	29.55	<sup>a</sup> Depo-Medrol [PF]	<sup>a</sup> Depo-Nisolone [FZ]

**■ METHYLPREDNISOLONE****Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5148Y	1	..	..	28.10	29.55	<sup>a</sup> Depo-Medrol [PF]	<sup>a</sup> Depo-Nisolone [FZ]

## ■ PREDNISOLONE

## prednisolone 1 mg tablet, 100

3152X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	16.56	18.01	<sup>a</sup> Predsolone [LN]
			<sup>B</sup> 1.00	17.56	18.01	<sup>a</sup> Panafcortelone [AS]

## prednisolone 25 mg tablet, 30

1916W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	17.85	19.30	Panafcortelone [AS]	Solone [IL]

## prednisolone 5 mg tablet, 60

1917X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	17.00	18.45	Panafcortelone [AS]	Solone [IL]

## ■ PREDNISOLONE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## prednisolone 1 mg tablet, 100

13888Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*19.67	21.12	<sup>a</sup> Predsolone [LN]
			<sup>B</sup> 2.00	*21.67	21.12	<sup>a</sup> Panafcortelone [AS]

## prednisolone 5 mg tablet, 60

14045F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	4	..	*20.55	22.00	Panafcortelone [AS]	Solone [IL]

## ■ PREDNISOLONE SODIUM PHOSPHATE

## prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

8285C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	19.85	21.30	<sup>a</sup> PredMix [LN]
			<sup>B</sup> 2.07	21.92	21.30	<sup>a</sup> Redipred [AS]

## ■ PREDNISOLONE SODIUM PHOSPHATE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

13837G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*26.25	27.70	<sup>a</sup> PredMix [LN]
			<sup>B</sup> 4.14	*30.39	27.70	<sup>a</sup> Redipred [AS]

## ■ PREDNISONE

## prednisone 1 mg tablet, 100

1934T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	16.50	17.95	<sup>a</sup> Predsone [LN]
			<sup>B</sup> 1.00	17.50	17.95	<sup>a</sup> Panafcort [AS]

## prednisone 25 mg tablet, 30

1936X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	16.64	18.09	Panafcort [AS]	Sone [IL]

## prednisone 5 mg tablet, 60

1935W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	16.91	18.36	Panafcort [AS]	Sone [IL]

## ■ PREDNISONE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## prednisone 1 mg tablet, 100

14043D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*19.55	21.00	<sup>a</sup> Predsone [LN]
			<sup>B</sup> 2.00	*21.55	21.00	<sup>a</sup> Panafcort [AS]

**prednisone 5 mg tablet, 60**

13944X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	4	..	*20.37	21.82	Panafcort [AS]	Sone [IL]

**▪ TRIAMCINOLONE****Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

5233K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	29.62	31.07	Kenacort-A10 [AS]

**▪ TRIAMCINOLONE****Restricted benefit**

Alopecia areata

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Chronic discoid lupus erythematosus

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Psoriasis

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

2990J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.62	31.07	Kenacort-A10 [AS]

**ANTIADRENAL PREPARATIONS***Anticorticosteroids***▪ OSILODROSTAT****Caution** The following should be assessed prior to receiving treatment and closely monitored throughout the treatment period:

1. QTc prolongation via an electrocardiogram
2. Hypocortisolism
3. Corticotroph tumour growth

**Note** Cortisol levels should be monitored at regular intervals, since hypocortisolism-related events can occur at any time during treatment.**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required**

Endogenous Cushing's syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a complete response after at least 26 weeks of treatment with this drug; OR
- Patient must have demonstrated a partial response after at least 26 weeks of treatment with this drug.

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purposes of administering this restriction, a complete response is defined as a mean urinary free cortisol (UFC) level of less than or equal to the upper limit of normal (ULN).

A partial response is defined as mean UFC level of greater than ULN but with at least 50% reduction from the baseline value. The mean UFC should be the average of at least two urine samples.

At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.

A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 5 repeats will be authorised.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

An application for the continuing treatment must be accompanied with the assessment of response conducted after 26 weeks from the first dose of osilodrostat and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for patients who meet the continuing restriction for PBS-subsidised treatment.

#### osilodrostat 1 mg tablet, 60

14723X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2562.60	31.60	Isturisa [RJ]

#### osilodrostat 5 mg tablet, 60

14729F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9822.60	31.60	Isturisa [RJ]

### ■ OSILODROSTAT

**Caution** The following should be assessed prior to receiving treatment and closely monitored throughout the treatment period:

1. QTc prolongation via an electrocardiogram
2. Hypocortisolism
3. Corticotroph tumour growth

**Note** Cortisol levels should be monitored at regular intervals, since hypocortisolism-related events can occur at any time during treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Endogenous Cushing's syndrome

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be at least one of: (i) persistent hypercortisolism after surgery, (ii) recurrent hypercortisolism after surgery, (iii) inappropriate for surgery, **AND**
- Patient must have active endogenous Cushing's Syndrome determined by a mean urinary free cortisol (UFC) level greater than 1.3 times the upper limit of normal (ULN); OR
- Patient must have undergone treatment for this condition with conventional therapies to control cortisol production resulting in an improved UFC level prior to applying for the initial authority application of this drug.

#### **Treatment criteria:**

- Must be treated by an endocrinologist.

#### **Population criteria:**

- Patient must be at least 18 years of age.

For the purposes of administering this restriction, the mean UFC is the average of at least two values being 1.3 times greater than the ULN.

Patient must undergo a dose titration period whereby responses must be assessed every 1-2 weeks until the mean UFC levels are within the normal range.

At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.

A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 6 repeats will be authorised.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

The condition is inappropriate for surgery if the patient:

- (i) has a medical contraindication for surgery;
- (ii) has inoperable tumours;
- (iii) has been determined that surgery is unlikely to reduce hypercortisolism;
- (iv) refuses surgery;
- (v) cannot access surgical treatment.

#### Authority required

Endogenous Cushing's syndrome

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2025, **AND**
- The condition must have been, at least one of: (i) persistent hypercortisolism after surgery, (ii) recurrent hypercortisolism after surgery, (iii) inappropriate for surgery, prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had active endogenous Cushing's Syndrome determined by a mean urinary free cortisol (UFC) level greater than 1.3 times the upper limit of normal (ULN) prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have demonstrated a complete response if they have received at least 26 weeks of initial non-PBS-subsidised therapy; OR
- Patient must have demonstrated a partial response if they have received at least 26 weeks of initial non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purposes of administering this restriction, a complete response is defined as a mean urinary free cortisol (UFC) level of less than or equal to the upper limit of normal (ULN).

A partial response is defined as mean UFC level of greater than ULN but with at least 50% reduction from the baseline value. The mean UFC should be the average of at least two urine samples.

Patient must undergo a dose titration period whereby responses must be assessed every 1-2 weeks until the mean UFC levels are within the normal range.

At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.

A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 6 repeats will be authorised.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

The condition is inappropriate for surgery if the patient:

- (i) has a medical contraindication for surgery;
- (ii) has inoperable tumours;
- (iii) has been determined that surgery is unlikely to reduce hypercortisolism;
- (iv) refuses surgery;
- (v) cannot access surgical treatment.

An application for the continuing treatment must be accompanied with the assessment of response conducted after 26 weeks from the first dose of osilodrostat and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for patients who meet the continuing restriction for PBS-subsidised treatment.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**osilodrostat 1 mg tablet, 60**

14714K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	2562.60	31.60	Isturisa [RJ]

**osilodrostat 5 mg tablet, 60**

14724Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	9822.60	31.60	Isturisa [RJ]

## ■ THYROID THERAPY

### THYROID PREPARATIONS

#### Thyroid hormones

## ■ LEVOTHYROXINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**levothyroxine sodium 125 microgram tablet, 200**

12830G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	24.94	26.39	Eltroxin [LT]



## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

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**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 75 microgram tablet, 2 x 100

12960D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	22.24	23.69	<sup>a</sup> LEVOXINE [RA]	<sup>a</sup> Thyrox [IX]

## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

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**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 100 microgram tablet, 2 x 100

12968M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	22.41	23.86	<sup>a</sup> LEVOXINE [RA]	<sup>a</sup> Thyrox [IX]

## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 50 microgram tablet, 2 x 100

12969N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	22.09	23.54	<sup>a</sup> LEVOXINE [RA]	<sup>a</sup> Thyrox [IX]

## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a



patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

#### **Restricted benefit**

For prescribing by certain health practitioners

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

#### **levothyroxine sodium 200 microgram tablet, 2 x 100**

12970P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	1	1	..	23.95	25.40	<sup>a</sup> LEVOXINE [RA]	<sup>a</sup> Thyrox [IX]

### ■ LEVOTHYROXINE

#### **Note Continuing Therapy Only:**

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**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.



#### **Restricted benefit**

For prescribing by certain health practitioners

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

#### **levothyroxine sodium 200 microgram tablet, 200**

2173J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	1	1	..	23.95	25.40	<sup>a</sup> APO-Levothyroxine [XT] <sup>a</sup> Levothyroxine Lup [GQ] <sup>b</sup> Eltroxin [LT]	<sup>a</sup> Eutroxsig [LN] <sup>a</sup> Levothyroxine Sandoz [SZ] <sup>b</sup> Levothox [AF]
			<sup>B</sup> 1.12	25.07	25.40	<sup>a</sup> Oroxine [AS]	

### ■ LEVOTHYROXINE

#### **Note Continuing Therapy Only:**

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**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.



#### **Restricted benefit**

For prescribing by certain health practitioners

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

#### **levothyroxine sodium 50 microgram tablet, 200**

2174K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	1	1	..	22.09	23.54	<sup>a</sup> APO-Levothyroxine [XT] <sup>a</sup> Levothyroxine Lup [GQ]	<sup>a</sup> Eutroxsig [LN] <sup>a</sup> Levothyroxine Sandoz [SZ]

<sup>b</sup> Eltroxin [LT]                      <sup>b</sup> Levothox [AF]  
<sup>B</sup>1.12      23.21      23.54      <sup>a</sup> Oroxine [AS]

## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.



### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 100 microgram tablet, 200

2175L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	1	1	..	22.41	23.86	<sup>a</sup> APO-Levothyroxine [XT] <sup>a</sup> Levothyroxine Lup [GQ] <sup>b</sup> Eltroxin [LT] <sup>a</sup> Oroxine [AS]	<sup>a</sup> Eutroxsig [LN] <sup>a</sup> Levothyroxine Sandoz [SZ] <sup>b</sup> Levothox [AF]
			<sup>B</sup> 1.11	23.52	23.86		

## ■ LEVOTHYROXINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.



### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 75 microgram tablet, 200

9287T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
 	1	1	..	22.24	23.69	<sup>a</sup> APO-Levothyroxine [XT] <sup>a</sup> Levothyroxine Lup [GQ] <sup>b</sup> Eltroxin [LT] <sup>a</sup> Oroxine [AS]	<sup>a</sup> Eutroxsig [LN] <sup>a</sup> Levothyroxine Sandoz [SZ] <sup>b</sup> Levothox [AF]
			<sup>B</sup> 1.13	23.37	23.69		

## ■ LIOTHYRONINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**6382**

Thyroid cancer

### Authority required (STREAMLINED)

**6410**

Hypothyroidism

### Clinical criteria:

- The treatment must be for replacement therapy, **AND**

- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

**Authority required (STREAMLINED)****6475**

Hypothyroidism

**Clinical criteria:**

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

2318B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	57.75	31.60	Tertroxin [AS]

**■ LIOTHYRONINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****14843**

Thyroid cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14844**

Hypothyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

**liothyronine sodium 20 microgram tablet, 100**

13966C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*102.05	31.60	Tertroxin [AS]

**ANTITHYROID PREPARATIONS***Thiouracils***■ PROPYLTHIOURACIL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**propylthiouracil 50 mg tablet, 100**

1955X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*44.93	31.60	PTU [FF]

**■ PROPYLTHIOURACIL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propylthiouracil 50 mg tablet, 100**

13836F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	2	..	*76.39	31.60	PTU [FF]

*Sulfur-containing imidazole derivatives*

## ■ CARBIMAZOLE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### carbimazole 5 mg tablet, 100

1153Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*34.15	31.60	<sup>a</sup> Neo-Mercazole [GH] <sup>a</sup> WP Carbimazole [TN]	<sup>a</sup> THIRAZOL [NB]

## ■ CARBIMAZOLE

### Note Continuing Therapy Only:

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### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### carbimazole 5 mg tablet, 100

13967D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	2	..	*54.83	31.60	<sup>a</sup> Neo-Mercazole [GH] <sup>a</sup> WP Carbimazole [TN]	<sup>a</sup> THIRAZOL [NB]

## ■ PANCREATIC HORMONES

### GLYCOGENOLYTIC HORMONES

#### Glycogenolytic hormones

## ■ GLUCAGON HYDROCHLORIDE

### glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

1449G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	51.10	31.60	GlucaGen Hypokit [NO]

### glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

5105Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	51.10	31.60	GlucaGen Hypokit [NO]

## ■ CALCIUM HOMEOSTASIS

### PARATHYROID HORMONES AND ANALOGUES

#### Parathyroid hormones and analogues

## ■ TERIPARATIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

### Authority required (STREAMLINED)

**15536**

Severe established osteoporosis

Treatment Phase: Continuing treatment

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

### Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

### teriparatide 250 microgram/mL injection, 2.4 mL pen device

14482F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*346.15	31.60	<sup>a</sup> Teriparatide Lupin [GQ]	<sup>a</sup> Terrosa [FX]

## ■ TERIPARATIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****12492**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority required (STREAMLINED)****12270**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

14093R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	177.30	31.60	<sup>a</sup> Teriparatide Lupin [GQ]	<sup>a</sup> Terrosa [FX]

**ANTI-PARATHYROID AGENTS***Calcitonin preparations***■ CALCITONIN SALMON**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note Continuing Therapy Only:**

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**Authority required**

Symptomatic Paget disease of bone

**Clinical criteria:**

- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**Authority required**

Hypercalcaemia

**Clinical criteria:**

## ANTIINFECTIVES FOR SYSTEMIC USE

- The treatment must be initiated in a hospital, **AND**
- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

### calcitonin salmon 100 units/mL injection, 5 x 1 mL ampoules

2997R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*128.37	31.60	Miacalcic 100 [EU]

### Other anti-parathyroid agents

#### ■ CINACALCET

##### Authority required (STREAMLINED)

**10068**

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

##### **Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; OR
- Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

### cinacalcet 30 mg tablet, 28

9157Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	34.70	31.60	<sup>a</sup> Cinacalcet Viatris [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

### cinacalcet 60 mg tablet, 28

9158B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	55.94	31.60	<sup>a</sup> Cinacalcet Viatris [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

### cinacalcet 90 mg tablet, 28

9159C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	77.18	31.60	<sup>a</sup> Cinacalcet Viatris [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

## ■ ANTIINFECTIVES FOR SYSTEMIC USE

## ■ ANTIBACTERIALS FOR SYSTEMIC USE

### TETRACYCLINES

#### *Tetracyclines*

#### ■ DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

### doxycycline 100 mg modified release capsule, 7

2708M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	<sup>B</sup> 1.54	17.69	17.60	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 2.95	19.10	17.60	<sup>a</sup> Doryx [YN]

### doxycycline 100 mg modified release capsule, 7

3322W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	<sup>B</sup> 1.54	17.69	17.60	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 2.95	19.10	17.60	<sup>a</sup> Doryx [YN]

### doxycycline 100 mg tablet, 7

2709N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	16.15	17.60	<sup>a</sup> APX-Doxycycline [TX]	<sup>a</sup> Doxsig [RW]
						<sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxylin 100 [AF]

### doxycycline 100 mg tablet, 7

3321T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.15	17.60	<sup>a</sup> APX-Doxycycline [TX]	<sup>a</sup> Doxsig [RW]
						<sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 7**

5082L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.15	17.60	<sup>a</sup> Doxycycline Sandoz [HX]

**doxycycline 100 mg tablet, 7**

9105F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	1	..	16.15	17.60	<sup>a</sup> Doxycycline Sandoz [HX]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Urethritis

**doxycycline 100 mg modified release capsule, 21**

2715X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	<sup>B</sup> 3.22	24.74	22.97	<sup>a</sup> Mayne Pharma Doxycycline [YT]

**doxycycline 100 mg tablet, 7**

2714W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	..	..	*21.54	22.99	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 7**

9108J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*21.54	22.99	<sup>a</sup> Doxycycline Sandoz [HX]

**doxycycline 100 mg tablet, 21**

10176N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	21.52	22.97	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> Doxylin 100 [AF]	<sup>a</sup> Doxsig [RW]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Severe acne

**doxycycline 100 mg modified release capsule, 7**

10777F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	<sup>B</sup> 6.16	*30.39	25.68	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 11.80	*36.03	25.68	<sup>a</sup> Doryx [YN]

**doxycycline 100 mg tablet, 7**

10779H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*24.23	25.68	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 7**

10781K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*24.23	25.68	<sup>a</sup> Doxycycline Sandoz [HX]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Pelvic inflammatory disease

**doxycycline 100 mg modified release capsule, 7**

2703G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	..	<sup>B</sup> 6.16	*30.39	25.68	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 11.80	*36.03	25.68	<sup>a</sup> Doryx [YN]

**doxycycline 100 mg tablet, 7**

2702F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*24.23	25.68	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 7**

9107H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*24.23	25.68	<sup>a</sup> Doxycycline Sandoz [HX]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**doxycycline 100 mg modified release capsule, 7**

14443E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	2	<sup>B</sup> 12.32	*47.31	31.60	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 23.60	*58.59	31.60	<sup>a</sup> Doryx [YN]

**doxycycline 100 mg tablet, 7**

14480D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	8	2	..	*34.99	31.60	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 100 [AF]

**doxycycline 100 mg tablet, 7**

14511R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	2	..	*34.99	31.60	<sup>a</sup> Doxycycline Sandoz [HX]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Bronchiectasis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Chronic bronchitis

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Severe acne

**doxycycline 50 mg modified release capsule, 25**

2707L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	<sup>B</sup> 2.58	18.92	17.79	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 5.00	21.34	17.79	<sup>a</sup> Doryx [YN]

**doxycycline 50 mg tablet, 25**

2711Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.34	17.79	<sup>a</sup> APX-Doxycycline [TX] <sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxsig [RW] <sup>a</sup> Doxylin 50 [AF]

**doxycycline 50 mg tablet, 25**

9106G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.34	17.79	<sup>a</sup> Doxycycline Sandoz [HX]

**■ DOXYCYCLINE**

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

Bronchiectasis



**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Chronic bronchitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 8 years or older.

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**doxycycline 50 mg modified release capsule, 25**

14484H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	<sup>B</sup> 5.16	*24.39	20.68	<sup>a</sup> Mayne Pharma Doxycycline [YT]
			<sup>B</sup> 10.00	*29.23	20.68	<sup>a</sup> Doryx [YN]

**doxycycline 50 mg tablet, 25**

14307B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*19.23	20.68	<sup>a</sup> APX-Doxycycline [TX]	<sup>a</sup> Doxsig [RW]
						<sup>a</sup> DOXYCYCLINE-WGR [WG]	<sup>a</sup> Doxylin 50 [AF]

**doxycycline 50 mg tablet, 25**

14513W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*19.23	20.68	<sup>a</sup> Doxycycline Sandoz [HX]

**■ MINOCYCLINE**

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

**minocycline 50 mg tablet, 60**

1616C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.61	24.06	<sup>a</sup> Akamin 50 [AF]
			<sup>B</sup> 3.23	25.84	24.06	<sup>a</sup> Minomycin-50 [AS]

**■ MINOCYCLINE**

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be responding to other tetracyclines.

**minocycline 50 mg tablet, 60**

14483G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*31.77	31.60	<sup>a</sup> Akamin 50 [AF]
			<sup>B</sup> 6.46	*38.23	31.60	<sup>a</sup> Minomycin-50 [AS]

**BETA-LACTAM ANTIBACTERIALS, PENICILLINS***Penicillins with extended spectrum*

## ■ AMOXICILLIN

## amoxicillin 250 mg capsule, 20

3301R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> Alphamox 250 [AF] <sup>a</sup> APO-Amoxycillin [TX]	<sup>a</sup> AMILOXYN [RF] <sup>a</sup> Cilamox [AL]
			<sup>B</sup> 4.68	20.85	17.62	<sup>a</sup> Amoxil [AS]	

## amoxicillin 500 mg capsule, 20

3300Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> Alphamox 500 [AF] <sup>a</sup> AMOXICILLIN-WGR [WG]  <sup>a</sup> Amoxycillin Sandoz [SZ] <sup>a</sup> Blooms The Chemist Amoxicillin [BG]	<sup>a</sup> AMILOXYN [RF] <sup>a</sup> Amoxycillin generichealth 500 [GQ] <sup>a</sup> APO-Amoxycillin [TX] <sup>a</sup> Cilamox [AL]
			<sup>B</sup> 4.67	20.84	17.62	<sup>a</sup> Amoxil [AS]	

## amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

5225B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#19.80	21.67	Maxamox [SZ]

## amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

8705E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	‡1	1	..	#19.80	21.67	Maxamox [SZ]

## amoxicillin 100 mg/mL powder for oral liquid, 20 mL

1888J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	‡1	1	<sup>S</sup> 0.53	#23.47	24.81	Amoxil [AS]

## amoxicillin 100 mg/mL powder for oral liquid, 20 mL

3310F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	<sup>S</sup> 0.53	#23.47	24.81	Amoxil [AS]

## amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

1886G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	‡1	1	..	#19.53	21.40	<sup>a</sup> Amoxycillin Sandoz [SZ] <sup>a</sup> NOUMED AMOXICILLIN [VO]	<sup>a</sup> APO-Amoxycillin [TX]
			<sup>B</sup> 4.55	#24.08	21.40	<sup>a</sup> Amoxil [AS]	

## amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

3302T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	<sup>a</sup> Amoxycillin Sandoz [SZ] <sup>a</sup> NOUMED AMOXICILLIN [VO]	<sup>a</sup> APO-Amoxycillin [TX]
			<sup>B</sup> 4.55	#24.08	21.40	<sup>a</sup> Amoxil [AS]	

## amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

1887H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	‡1	1	..	#19.53	21.40	<sup>a</sup> AMOXICILLIN-WGR [WG] <sup>a</sup> APO-Amoxycillin [TX] <sup>a</sup> NOUMED AMOXICILLIN [VO]	<sup>a</sup> Amoxycillin Sandoz [SZ] <sup>a</sup> Cilamox [AL]
			<sup>B</sup> 4.32	#23.85	21.40	<sup>a</sup> Amoxil Forte [AS]	

## amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

3393N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	<sup>a</sup> AMOXICILLIN-WGR [WG] <sup>a</sup> APO-Amoxycillin [TX] <sup>a</sup> NOUMED AMOXICILLIN [VO]	<sup>a</sup> Amoxycillin Sandoz [SZ] <sup>a</sup> Cilamox [AL]
			<sup>B</sup> 4.32	#23.85	21.40	<sup>a</sup> Amoxil Forte [AS]	

## ■ AMOXICILLIN

Authority required (STREAMLINED)

10416

Community acquired pneumonia

**Clinical criteria:**

- Patient must have community acquired pneumonia.

## amoxicillin 1 g tablet, 14

12002Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.37	17.82	<sup>a</sup> Amoxycillin Sandoz [BG]
			<sup>B</sup> 1.00	17.37	17.82	<sup>a</sup> Maxamox [SZ]

## ■ AMOXICILLIN

**Restricted benefit**

Chronic bronchitis

**Clinical criteria:**

- Patient must have acute exacerbations of the condition.

**amoxicillin 1 g tablet, 14**

8581P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.37	17.82	<sup>a</sup> Amoxycillin Sandoz [BG]
			<sup>B</sup> 1.00	17.37	17.82	<sup>a</sup> Maxamox [SZ]

## ■ AMOXICILLIN

**Authority required**

Infection suspected or proven to be due to a susceptible organism

**Clinical criteria:**

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

9714G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	±1	1	..	#23.47	25.34	Amoxil [AS]

## ■ AMOXICILLIN

**Authority required (STREAMLINED)****10402**

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; OR
- Patient must have pyelonephritis; OR
- Patient must have a tooth avulsion; OR
- Patient must have salmonella enteritis; OR
- Patient must have community acquired pneumonia; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 500 mg capsule, 20**

11947T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*18.89	20.34	<sup>a</sup> Alphamox 500 [AF]	<sup>a</sup> AMILOXYN [RF]
						<sup>a</sup> AMOXICILLIN-WGR [WG]	<sup>a</sup> Amoxycillin generichealth 500 [GQ]
						<sup>a</sup> Amoxycillin Sandoz [SZ]	<sup>a</sup> APO-Amoxycillin [TX]
						<sup>a</sup> Blooms The Chemist Amoxicillin [BG]	<sup>a</sup> Cilamox [AL]
			<sup>B</sup> 9.34	*28.23	20.34	<sup>a</sup> Amoxil [AS]	

## ■ AMOXICILLIN

**Authority required (STREAMLINED)****10404**

Infection

**Clinical criteria:**

- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 250 mg capsule, 20**

11998L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*18.89	20.34	<sup>a</sup> Alphamox 250 [AF]	<sup>a</sup> AMILOXYN [RF]
						<sup>a</sup> APO-Amoxycillin [TX]	<sup>a</sup> Cilamox [AL]
			<sup>B</sup> 9.36	*28.25	20.34	<sup>a</sup> Amoxil [AS]	

## ■ AMOXICILLIN

**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**amoxicillin 250 mg capsule, 20**

1884E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.17	17.62	<sup>a</sup> Alphamox 250 [AF]	<sup>a</sup> AMILOXYN [RF]
						<sup>a</sup> APO-Amoxycillin [TX]	<sup>a</sup> Cilamox [AL]
			<sup>B</sup> 4.68	20.85	17.62	<sup>a</sup> Amoxil [AS]	

**amoxicillin 500 mg capsule, 20**

1889K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.17	17.62	<sup>a</sup> Alphamox 500 [AF]	<sup>a</sup> AMILOXYN [RF]
						<sup>a</sup> AMOXICILLIN-WGR [WG]	<sup>a</sup> Amoxycillin generichealth 500 [GQ]

<sup>a</sup> Amoxycillin Sandoz [SZ]<sup>a</sup> APO-Amoxycillin [TX]<sup>a</sup> Blooms The Chemist  
Amoxicillin [BG]<sup>a</sup> Cilamox [AL]<sup>B</sup>4.67 20.84 17.62 <sup>a</sup> Amoxil [AS]**Beta-lactamase sensitive penicillins****■ BENZATHINE BENZYL PENICILLIN****benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

11723B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	216.87	31.60	Bicillin L-A [PF]

**benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

11735P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	216.87	31.60	Bicillin L-A [PF]

**■ BENZATHINE BENZYL PENICILLIN****Note** Pharmaceutical benefits that have the brand Extencilline Benzathine Benzylpenicillin (France) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

2267H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	335.98	31.60	<sup>a</sup> Bicillin L-A [PF]

**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

5027N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	335.98	31.60	<sup>a</sup> Bicillin L-A [PF]

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack**

13790T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	10	..	..	*511.97	31.60	<sup>a</sup> Extencilline Benzathine Benzylpenicillin (France) [YO]

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack**

13816E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	..	..	*511.97	31.60	<sup>a</sup> Extencilline Benzathine Benzylpenicillin (France) [YO]

**■ BENZYL PENICILLIN****benzylpenicillin 600 mg injection, 1 vial**

1775K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	10	1	..	*72.87	31.60	BenPen [CS]

**benzylpenicillin 600 mg injection, 1 vial**

3398W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	10	..	..	*72.87	31.60	BenPen [CS]

**benzylpenicillin 3 g injection, 1 vial**

3399X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	10	..	..	*109.27	31.60	BenPen [CS]

**■ BENZYL PENICILLIN****Caution** If prescribed for sepsis (or suspected sepsis) by an authorised PBS prescriber who is not a medical practitioner, the decision to prescribe this benefit is to be shared with a medical practitioner.**benzylpenicillin 3 g injection, 1 vial**

2647H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	10	..	..	*109.27	31.60	BenPen [CS]

**■ PHENOXYMETHYL PENICILLIN****phenoxymethylpenicillin 250 mg capsule, 50**

1789E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 250 mg capsule, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3363B	1	..	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 500 mg capsule, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2965C	1	..	..	18.92	20.37	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 500 mg capsule, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3364C	1	..	..	18.92	20.37	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
5012T	2	..	..	*25.17	26.62	Cilicaine V [AF]	

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
9143F	2	1	..	*25.17	26.62	Cilicaine V [AF]	

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
5024K	2	..	..	*#26.37	28.24	Phenoxymethylpenicillin-AFT [AE]	

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
8976K	2	1	..	*#26.37	28.24	Phenoxymethylpenicillin-AFT [AE]	

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
5029Q	2	..	..	*#28.31	30.18	Phenoxymethylpenicillin-AFT [AE]	

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
8977L	2	1	..	*#28.31	30.18	Phenoxymethylpenicillin-AFT [AE]	

**phenoxymethylpenicillin 250 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
1787C	2	..	..	*18.85	20.30	Aspecillin VK [AF]	

**phenoxymethylpenicillin 250 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
3360W	2	..	..	*18.85	20.30	Aspecillin VK [AF]	

**phenoxymethylpenicillin 500 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
3028J	2	..	..	*20.85	22.30	Aspecillin VK [AF]	

**phenoxymethylpenicillin 500 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
3361X	2	..	..	*20.85	22.30	Aspecillin VK [AF]	

**■ PHENOXYMETHYLPENICILLIN****Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg capsule, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13968E	2	5	..	*21.71	23.16	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 250 mg tablet, 25**

14044E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*24.23	25.68	Aspecillin VK [AF]

**■ PHENOXYMETHYLPENICILLIN****Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg capsule, 50**

1705R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.58	19.03	Cilicaine VK [AF]	LPV [IL]

**phenoxymethylpenicillin 250 mg tablet, 25**

1703P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.85	20.30	Aspecillin VK [AF]

*Beta-lactamase resistant penicillins***■ DICLOXACILLIN****Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

5096F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	18.17	19.62	<sup>a</sup> Dicloxacillin Mylan 250 [AL]	<sup>a</sup> DICLOXACILLIN VIATRIS 250 [MQ]
			<sup>B</sup> 1.86	20.03	19.62	<sup>a</sup> Distaph 250 [AF]	

**dicloxacillin 500 mg capsule, 24**

5097G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	21.56	23.01	<sup>a</sup> DICLOXACILLIN VIATRIS 500 [MQ]
			<sup>B</sup> 1.95	23.51	23.01	<sup>a</sup> Distaph 500 [AF]

**■ DICLOXACILLIN****Restricted benefit**

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

8121K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	18.17	19.62	<sup>a</sup> Dicloxacillin Mylan 250 [AL]	<sup>a</sup> DICLOXACILLIN VIATRIS 250 [MQ]
			<sup>B</sup> 1.86	20.03	19.62	<sup>a</sup> Distaph 250 [AF]	

**dicloxacillin 500 mg capsule, 24**

8122L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	21.56	23.01	<sup>a</sup> DICLOXACILLIN VIATRIS 500 [MQ]
			<sup>B</sup> 1.95	23.51	23.01	<sup>a</sup> Distaph 500 [AF]

**■ DICLOXACILLIN****Authority required (STREAMLINED)****6188**

Osteomyelitis

**dicloxacillin 500 mg capsule, 24**

10790X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*29.67	31.12	<sup>a</sup> DICLOXACILLIN VIATRIS 500 [MQ]
			<sup>B</sup> 3.90	*33.57	31.12	<sup>a</sup> Distaph 500 [AF]

**■ FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**flucloxacillin 1 g injection, 5 vials**

1525G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	22.60	24.05	Flucil [AS]

**flucloxacillin 1 g injection, 5 vials**

5095E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.60	24.05	Flucil [AS]

**FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 250 mg capsule, 24**

1526H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	17.73	19.18	<sup>a</sup> Flopen [AL] <sup>a</sup> Staphylex 250 [AF]	<sup>a</sup> Flopen Viatris [MQ]

**flucloxacillin 500 mg capsule, 24**

1527J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	22.15	23.60	<sup>a</sup> Flopen [AL] <sup>a</sup> Staphylex 500 [AF]	<sup>a</sup> Flopen Viatris [MQ]

**FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

5257Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	#23.56	25.43	Flucil [LN]

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

5258R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	#26.40	28.27	Flucil [LN]

**flucloxacillin 250 mg capsule, 24**

5090X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.73	19.18	<sup>a</sup> Flopen [AL] <sup>a</sup> Staphylex 250 [AF]	<sup>a</sup> Flopen Viatris [MQ]

**flucloxacillin 500 mg capsule, 24**

5091Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	22.15	23.60	<sup>a</sup> Flopen [AL] <sup>a</sup> Staphylex 500 [AF]	<sup>a</sup> Flopen Viatris [MQ]

**FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

Serious staphylococcal infection

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

9149M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	±1	1	..	#23.56	25.43	Flucil [LN]

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

9150N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	±1	1	..	#26.40	28.27	Flucil [LN]

**FLUCLOXACILLIN**

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority required (STREAMLINED)****6169**

Osteomyelitis

**flucloxacillin 500 mg capsule, 24**

10788T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*30.85	31.60	<sup>a</sup> Flopen [AL] <sup>a</sup> Staphylex 500 [AF]	<sup>a</sup> Flopen Viatris [MQ]

*Combinations of penicillins, incl. beta-lactamase inhibitors*

## ■ AMOXICILLIN + CLAVULANIC ACID

Authority required (STREAMLINED)**10413**

Infection

**Clinical criteria:**

- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have postpartum endometritis; OR
- Patient must have an exacerbation of bronchiectasis; OR
- Patient must have pyelonephritis; OR
- Patient must have pneumonia acquired in hospital or aged care; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

11933C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	..	..	*20.09	21.54	<sup>a</sup> Alphaclav Duo Forte Viatris [AL]	<sup>a</sup> AMCLAVOX DUO FORTE 875/125 [RW]
						<sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG]	<sup>a</sup> AmoxyClav generichealth 875/125 [HQ]
						<sup>a</sup> APO-Amoxycillin and Clavulanic Acid [TX]	<sup>a</sup> APO-AMOX/CLAV 875/125 [TW]
						<sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT]	<sup>a</sup> Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
						<sup>a</sup> Curam Duo Forte 875/125 [SZ]	
			<sup>B</sup> 13.56	*33.65	21.54	<sup>a</sup> Augmentin Duo forte [AS]	

## ■ AMOXICILLIN + CLAVULANIC ACID

Authority required (STREAMLINED)**10405**

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

11941L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	..	..	*19.49	20.94	<sup>a</sup> AlphaClav Duo [AF]	<sup>a</sup> Alphaclav Duo Viatris [AL]
						<sup>a</sup> AMCLAVOX DUO 500/125 [RW]	<sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG]
						<sup>a</sup> Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY]	<sup>a</sup> APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]
						<sup>a</sup> APO-AMOX/CLAV 500/125 [TW]	<sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT]
						<sup>a</sup> Curam Duo 500/125 [SZ]	
			<sup>B</sup> 10.82	*30.31	20.94	<sup>a</sup> Augmentin Duo [AS]	

## ■ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

**amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

1892N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	±1	1	..	#19.53	21.40	Curam [SZ]

**amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

8319W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	±1	1	..	#19.53	21.40	<sup>a</sup> Curam Duo [SZ]
			<sup>B</sup> 5.26	#24.79	21.40	<sup>a</sup> Augmentin Duo 400 [AS]

## ■ AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven



**amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

5009P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	Curam [SZ]

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

5008N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.47	17.92	<sup>a</sup> AlphaClav Duo [AF] <sup>a</sup> AMCLAVOX DUO 500/125 [RW] <sup>a</sup> Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY] <sup>a</sup> APO-AMOX/CLAV 500/125 [TW] <sup>a</sup> Curam Duo 500/125 [SZ]	<sup>a</sup> Alphaclav Duo Viatris [AL] <sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG] <sup>a</sup> APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] <sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT]
			<sup>B</sup> 5.41	21.88	17.92	<sup>a</sup> Augmentin Duo [AS]	

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

5006L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.77	18.22	<sup>a</sup> Alphaclav Duo Forte Viatris [AL] <sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG] <sup>a</sup> APO-Amoxycillin and Clavulanic Acid [TX] <sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT] <sup>a</sup> Curam Duo Forte 875/125 [SZ]	<sup>a</sup> AMCLAVOX DUO FORTE 875/125 [RW] <sup>a</sup> AmoxyClav generichealth 875/125 [HQ] <sup>a</sup> APO-AMOX/CLAV 875/125 [TW] <sup>a</sup> Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
			<sup>B</sup> 6.78	23.55	18.22	<sup>a</sup> Augmentin Duo forte [AS]	

**amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

5011R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	<sup>a</sup> Curam Duo [SZ]
			<sup>B</sup> 5.26	#24.79	21.40	<sup>a</sup> Augmentin Duo 400 [AS]

**AMOXICILLIN + CLAVULANIC ACID**

**Caution** Hepatotoxicity has been reported with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

Infections where resistance to amoxicillin is proven

**amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10**

1891M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.47	17.92	<sup>a</sup> AlphaClav Duo [AF] <sup>a</sup> AMCLAVOX DUO 500/125 [RW] <sup>a</sup> Amoxycillin/Clavulanic Acid 500/125 APOTEX [TY] <sup>a</sup> APO-AMOX/CLAV 500/125 [TW] <sup>a</sup> Curam Duo 500/125 [SZ]	<sup>a</sup> Alphaclav Duo Viatris [AL] <sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG] <sup>a</sup> APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] <sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT]
			<sup>B</sup> 5.41	21.88	17.92	<sup>a</sup> Augmentin Duo [AS]	

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

8254K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.77	18.22	<sup>a</sup> Alphaclav Duo Forte Viatris [AL] <sup>a</sup> AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG] <sup>a</sup> APO-Amoxycillin and Clavulanic Acid [TX] <sup>a</sup> APX-Amoxicillin/Clavulanic Acid [XT] <sup>a</sup> Curam Duo Forte 875/125 [SZ]	<sup>a</sup> AMCLAVOX DUO FORTE 875/125 [RW] <sup>a</sup> AmoxyClav generichealth 875/125 [HQ] <sup>a</sup> APO-AMOX/CLAV 875/125 [TW] <sup>a</sup> Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG]
			<sup>B</sup> 6.78	23.55	18.22	<sup>a</sup> Augmentin Duo forte [AS]	

**OTHER BETA-LACTAM ANTIBACTERIALS**

*First-generation cephalosporins*

## ■ CEFALEXIN

## cefaletin 250 mg capsule, 20

3317N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 4.72	20.89	17.62	<sup>a</sup> Keflex [AS]	

## cefaletin 500 mg capsule, 20

3318P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Blooms The Chemist Cefalexin [BG]
						<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Cephalax 500 [CR]
						<sup>a</sup> Cephalaxin generichealth [GQ]	<sup>a</sup> CEPHALEXIN-WGR [WG]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> NOUMED CEFALEXIN [VO]
			<sup>B</sup> 6.28	22.45	17.62	<sup>a</sup> Keflex [AS]	

## cefaletin 125 mg/5 mL powder for oral liquid, 100 mL

3094W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	‡1	1	..	#19.53	21.40	<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Ibilex 125 [AF]
			<sup>B</sup> 4.66	#24.19	21.40	<sup>a</sup> Keflex [AS]	

## cefaletin 125 mg/5 mL powder for oral liquid, 100 mL

3319Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Ibilex 125 [AF]
			<sup>B</sup> 4.66	#24.19	21.40	<sup>a</sup> Keflex [AS]	

## cefaletin 250 mg/5 mL powder for oral liquid, 100 mL

3095X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	‡1	1	..	#19.63	21.50	<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 6.01	#25.64	21.50	<sup>a</sup> Keflex [AS]	

## cefaletin 250 mg/5 mL powder for oral liquid, 100 mL

3320R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#19.63	21.50	<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 6.01	#25.64	21.50	<sup>a</sup> Keflex [AS]	

## ■ CEFALEXIN

Authority required (STREAMLINED)

6188

Osteomyelitis

## cefaletin 500 mg capsule, 20

10778G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*18.89	20.34	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Blooms The Chemist Cefalexin [BG]
						<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Cephalax 500 [CR]
						<sup>a</sup> Cephalaxin generichealth [GQ]	<sup>a</sup> CEPHALEXIN-WGR [WG]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> NOUMED CEFALEXIN [VO]
			<sup>B</sup> 12.56	*31.45	20.34	<sup>a</sup> Keflex [AS]	

## ■ CEFALEXIN

Authority required (STREAMLINED)

10410

Infection

**Clinical criteria:**

- Patient must have a pin-site infection; OR
  - Patient must have an infection following cardiac device insertion; OR
  - Patient must have acute otitis externa; OR
  - Patient must have streptococcal pharyngitis or tonsillitis; OR
  - Patient must have mastitis; OR
  - Patient must have periorbital (preseptal) cellulitis; OR
  - Patient must have acute rheumatic fever; OR
  - Patient must have a diabetic foot infection; OR
  - Patient must have a widespread infection of dermatitis; OR
  - Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
  - Patient must have impetigo; OR
  - Patient must have pyelonephritis; OR
  - Patient must have a condition requiring prolonged oral antibiotic therapy.
- Midwives may prescribe under this item for the treatment of mastitis only.

**cefalexin 500 mg capsule, 20**

11934D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	..	..	*18.89	20.34	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Blooms The Chemist Cefalexin [BG]
						<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Cephalax 500 [CR]
						<sup>a</sup> Cephalexin generichealth [GQ]	<sup>a</sup> CEPHALEXIN-WGR [WG]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> NOUMED CEFALEXIN [VO]
						<sup>a</sup> Keflex [AS]	
			<sup>B</sup> 12.56	*31.45	20.34		

**■ CEFALEXIN****Authority required (STREAMLINED)****10412**

Infection

**Clinical criteria:**

- Patient must have impaired renal function, **AND**
- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.

**cefalexin 250 mg capsule, 20**

11963P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	..	..	*18.89	20.34	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 9.44	*28.33	20.34	<sup>a</sup> Keflex [AS]	

**■ CEFALEXIN****Authority required (STREAMLINED)****4243**

Prophylaxis of urinary tract infection

**cefalexin 250 mg capsule, 20**

2655R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.89	20.34	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 9.44	*28.33	20.34	<sup>a</sup> Keflex [AS]	

**■ CEFALEXIN****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**cefalexin 250 mg capsule, 20**

3058Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.17	17.62	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Ibilex 250 [AF]
			<sup>B</sup> 4.72	20.89	17.62	<sup>a</sup> Keflex [AS]	

**cefalexin 500 mg capsule, 20**

3119E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.17	17.62	<sup>a</sup> APO-Cephalexin [TX]	<sup>a</sup> Blooms The Chemist Cefalexin [BG]
						<sup>a</sup> Cefalexin Sandoz [SZ]	<sup>a</sup> Cephalax 500 [CR]
						<sup>a</sup> Cephalexin generichealth [GQ]	<sup>a</sup> CEPHALEXIN-WGR [WG]
						<sup>a</sup> Ibilex 500 [AF]	<sup>a</sup> NOUMED CEFALEXIN [VO]
						<sup>a</sup> Keflex [AS]	
			<sup>B</sup> 6.28	22.45	17.62		

**■ CEFAZOLIN****Restricted benefit**

Cellulitis

**cefazolin 2 g injection, 10 vials**

12115P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.68	31.60	Cephazolin Viatrix [AL]

■ **CEFAZOLIN****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cefazolin 1 g injection, 5 vials**

14698N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b> <b>MW</b>	2	..	..	*22.15	23.60	Cefazolin-AFT [AE]	

**cefazolin 2 g injection, 10 vials**

14694J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b> <b>MW</b>	1	..	..	46.68	31.60	Cephazolin Viatris [AL]	

■ **CEFAZOLIN****Restricted benefit**

Cellulitis

**cefazolin 1 g injection, 5 vials**

1799Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	..	..	*22.15	23.60	Cefazolin-AFT [AE]	

■ **CEFAZOLIN****Restricted benefit**

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cefazolin 1 g injection, 5 vials**

1797N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	..	..	*22.15	23.60	Cefazolin-AFT [AE]	

**cefazolin 2 g injection, 10 vials**

12118T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	..	..	46.68	31.60	Cephazolin Viatris [AL]	

*Second-generation cephalosporins*■ **CEFACTOR**

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

**cefactor 125 mg/5 mL powder for oral liquid, 100 mL**

2460L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#20.53	22.40	<sup>a</sup> Aclor 125 [MQ]	<sup>a</sup> Cefactor SUN [RA]
						<sup>a</sup> Keflor [AF]	
			<sup>B</sup> 7.85	#28.38	22.40	<sup>a</sup> Ceclor [AL]	

**cefactor 125 mg/5 mL powder for oral liquid, 100 mL**

5046N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	‡1	..	..	#20.53	22.40	<sup>a</sup> Aclor 125 [MQ]	<sup>a</sup> Cefactor SUN [RA]
						<sup>a</sup> Keflor [AF]	
			<sup>B</sup> 7.85	#28.38	22.40	<sup>a</sup> Ceclor [AL]	

**cefactor 250 mg/5 mL powder for oral liquid, 75 mL**

2461M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#20.53	22.40	<sup>a</sup> Aclor 250 [MQ]	<sup>a</sup> Cefactor SUN [RA]
						<sup>a</sup> Keflor [AF]	
			<sup>B</sup> 7.85	#28.38	22.40	<sup>a</sup> Ceclor [AL]	

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

5047P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#20.53	22.40	<sup>a</sup> Aclor 250 [MQ]	<sup>a</sup> Cefaclor SUN [RA]
			<sup>B</sup> 7.85	#28.38	22.40	<sup>a</sup> Keflor [AF]	<sup>a</sup> Ceclor [AL]

**cefaclor 375 mg modified release tablet, 10**

1169M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	17.37	18.82	<sup>a</sup> Karlor CD [MQ]	<sup>a</sup> Keflor CD [AF]
			<sup>B</sup> 7.85	25.22	18.82	<sup>a</sup> Ceclor CD [AL]	

**cefaclor 375 mg modified release tablet, 10**

5045M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.37	18.82	<sup>a</sup> Karlor CD [MQ]	<sup>a</sup> Keflor CD [AF]
			<sup>B</sup> 7.85	25.22	18.82	<sup>a</sup> Ceclor CD [AL]	

**■ CEFUROXIME****cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL**

13643C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡2	1	..	*#116.09	31.60	Zinnat (UK) [RQ]

**cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL**

13653N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡2	..	..	*#116.09	31.60	Zinnat (UK) [RQ]

**cefuroxime 250 mg tablet, 14**

5052X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	19.14	20.59	Pharmacor Cefuroxime [CR]

**cefuroxime 250 mg tablet, 14**

8292K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.14	20.59	Pharmacor Cefuroxime [CR]

**cefuroxime 250 mg tablet, 20**

11227X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	21.56	23.01	<sup>a</sup> Pharmacor Cefuroxime [CR]
			<sup>B</sup> 3.90	25.46	23.01	<sup>a</sup> Zinnat [AS]

**cefuroxime 250 mg tablet, 20**

11228Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.56	23.01	<sup>a</sup> Pharmacor Cefuroxime [CR]
			<sup>B</sup> 3.90	25.46	23.01	<sup>a</sup> Zinnat [AS]

*Third-generation cephalosporins***■ CEFOTAXIME****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**cefotaxime 1 g injection, 10 vials**

1768C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	35.51	31.60	DBL Cefotaxime [PF]

**■ CEFOTAXIME****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cefotaxime 1 g injection, 10 vials**

1758M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	35.51	31.60	DBL Cefotaxime [PF]

**▪ CEFTRIAXONE****Restricted benefit**

Gonorrhoea

**ceftriaxone 500 mg injection, 1 vial**

9058R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	16.15	17.60	Ceftriaxone-AFT [AE]

**▪ CEFTRIAXONE****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 500 mg injection, 1 vial**

14697M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	5	..	..	*26.92	28.37	Ceftriaxone-AFT [AE]

**ceftriaxone 1 g injection, 10 vials**

14700Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	0.5	..	..	*32.52	31.60	Ceftriaxone Viatrix [AL]

**▪ CEFTRIAXONE****Restricted benefit**

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 500 mg injection, 1 vial**

1783W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	..	..	*26.92	28.37	Ceftriaxone-AFT [AE]

**ceftriaxone 1 g injection, 10 vials**

12114N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	0.5	..	..	*32.52	31.60	Ceftriaxone Viatrix [AL]

**▪ CEFTRIAXONE**

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 2 g injection, 10 vials**

14699P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	0.5	..	..	*32.65	31.60	<sup>a</sup> Ceftriaxone Viatrix [AL]

**ceftriaxone 2 g injection, 5 vials**

14695K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	1	..	..	27.28	28.73	<sup>a</sup> Ceftriaxone Viatris [AL]

**■ CEFTRIAXONE**

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

**Restricted benefit**

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 2 g injection, 10 vials**

12112L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	0.5	..	..	*32.65	31.60	<sup>a</sup> Ceftriaxone Viatris [AL]

**ceftriaxone 2 g injection, 5 vials**

11169W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	27.28	28.73	<sup>a</sup> Ceftriaxone Viatris [AL]

**SULFONAMIDES AND TRIMETHOPRIM***Trimethoprim and derivatives***■ TRIMETHOPRIM****trimethoprim 300 mg tablet, 7**

2922T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b> <b>MW</b>	1	1	..	16.15	17.60	<sup>a</sup> Trimethoprim Viatris [MQ]	<sup>a</sup> TRIMETHOPRIM-WGR [WG]
			<sup>B</sup> 2.76	18.91	17.60	<sup>a</sup> Alprim [AF]	
			<sup>B</sup> 3.98	20.13	17.60	<sup>a</sup> Triprim [RW]	

**■ TRIMETHOPRIM****Authority required (STREAMLINED)**

**4243**

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

2666H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.85	20.30	<sup>a</sup> Trimethoprim Viatris [MQ]	<sup>a</sup> TRIMETHOPRIM-WGR [WG]
			<sup>B</sup> 5.52	*24.37	20.30	<sup>a</sup> Alprim [AF]	
			<sup>B</sup> 7.96	*26.81	20.30	<sup>a</sup> Triprim [RW]	

**■ TRIMETHOPRIM****Restricted benefit**

Prostatitis

**trimethoprim 300 mg tablet, 7**

10785P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	..	..	*24.23	25.68	<sup>a</sup> Trimethoprim Viatris [MQ]	<sup>a</sup> TRIMETHOPRIM-WGR [WG]
			<sup>B</sup> 11.04	*35.27	25.68	<sup>a</sup> Alprim [AF]	
			<sup>B</sup> 15.92	*40.15	25.68	<sup>a</sup> Triprim [RW]	

*Combinations of sulfonamides and trimethoprim, incl. derivatives***■ TRIMETHOPRIM + SULFAMETHOXAZOLE**

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3103H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	1	..	21.76	23.21	Seprin [RW]

# ANTIINFECTIVES FOR SYSTEMIC USE

## trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

3391L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	21.76	23.21	Seprin [RW]

## trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

2951H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	16.15	17.60	<sup>a</sup> Bactrim DS [XO]	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 4.17	20.32	17.60	<sup>a</sup> Seprin Forte [RW]	

## trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

3390K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.15	17.60	<sup>a</sup> Bactrim DS [XO]	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 4.17	20.32	17.60	<sup>a</sup> Seprin Forte [RW]	

## ■ TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**Authority required (STREAMLINED)**

**6201**

Prophylaxis of Pneumocystis jiroveci pneumonia

## trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

10784N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*21.54	22.99	<sup>a</sup> Bactrim DS [XO]	<sup>a</sup> Resprim Forte [AF]
			<sup>B</sup> 12.51	*34.05	22.99	<sup>a</sup> Seprin Forte [RW]	

## MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

### Macrolides

## ■ AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Trachoma

## azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#29.06	30.93	Zithromax [PF]

## azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.85	19.30	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Viatris [AL] <sup>a</sup> ZITHRO [RW]	<sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> AZITHROMYCIN-WGR [WG] <sup>a</sup> Zithromax [PF]

## ■ AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Urethritis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

**Restricted benefit**

Cervicitis

**Clinical criteria:**

- The condition must be uncomplicated and due to Chlamydia trachomatis.

## azithromycin 500 mg tablet, 2

8200N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	17.85	19.30	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Viatris [AL] <sup>a</sup> ZITHRO [RW]	<sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> AZITHROMYCIN-WGR [WG] <sup>a</sup> Zithromax [PF]

## ■ CLARITHROMYCIN

### clarithromycin 250 mg tablet, 14

8318T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.12	18.57	<sup>a</sup> Clarithro 250 [RW] <sup>a</sup> Kalixocin [AF]	<sup>a</sup> Clarithromycin Sandoz [SZ] <sup>a</sup> NOUMED CLARITHROMYCIN [VO]
			<sup>B</sup> 3.33	20.45	18.57	<sup>a</sup> Klacid [GO]	



## ■ CLARITHROMYCIN

**Restricted benefit**

Bordetella pertussis

**Restricted benefit**

Atypical mycobacterial infections

**clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL**

9192T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	#32.73	31.60	Klacid [GO]

## ■ ERYTHROMYCIN

**erythromycin 250 mg enteric capsule, 25**

1404X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	25.46	26.91	Mayne Pharma Erythromycin [YT]

**erythromycin 250 mg enteric capsule, 25**

3325B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	25.46	26.91	Mayne Pharma Erythromycin [YT]

## ■ ERYTHROMYCIN

**Authority required (STREAMLINED)****6160**

Severe acne

**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

10780J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*37.47	31.60	Mayne Pharma Erythromycin [YT]

## ■ ERYTHROMYCIN

**Authority required (STREAMLINED)****15710**

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

14409J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*61.47	31.60	Mayne Pharma Erythromycin [YT]

## ■ ERYTHROMYCIN ETHYLSUCCINATE

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

2424N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	±1	1	..	#21.49	23.36	E-Mycin 200 [AF]

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

3334L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	#21.49	23.36	E-Mycin 200 [AF]

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

2428T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	±1	1	..	#22.73	24.60	E-Mycin 400 [AF]

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

3337P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	#22.73	24.60	E-Mycin 400 [AF]

## ■ ROXITHROMYCIN

**roxithromycin 150 mg tablet, 10**

5260W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.48	17.93	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 150 [RW]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

<sup>a</sup> ROXITHROMYCIN-WGR [WG]**roxithromycin 300 mg tablet, 5**

5261X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.48	17.93	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 300 [RW] <sup>a</sup> ROXITHROMYCIN-WGR [WG]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

**■ ROXITHROMYCIN****Authority required (STREAMLINED)****10404**

Infection

**Clinical criteria:**

- Patient must have a condition requiring prolonged oral antibiotic therapy.

**roxithromycin 150 mg tablet, 10**

12001P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*19.51	20.96	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 150 [RW] <sup>a</sup> ROXITHROMYCIN-WGR [WG]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

**roxithromycin 300 mg tablet, 5**

11993F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*19.51	20.96	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 300 [RW] <sup>a</sup> ROXITHROMYCIN-WGR [WG]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

**■ ROXITHROMYCIN****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**roxithromycin 150 mg tablet, 10**

1760P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.48	17.93	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 150 [RW] <sup>a</sup> ROXITHROMYCIN-WGR [WG]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

**roxithromycin 300 mg tablet, 5**

8016X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.48	17.93	<sup>a</sup> APO-Roxithromycin [TX] <sup>a</sup> Roxar 300 [RW] <sup>a</sup> ROXITHROMYCIN-WGR [WG]	<sup>a</sup> APX-Roxithromycin [TY] <sup>a</sup> Roxithromycin Sandoz [SZ]

**Lincosamides****■ CLINDAMYCIN****Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

5057E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.94	19.39	<sup>a</sup> APO-Clindamycin [TX] <sup>a</sup> Clindamycin LU [XT] <sup>a</sup> Clindamylk [AF]	<sup>a</sup> Calindamin [RW] <sup>a</sup> CLINDAMYCIN-WGR [WG] <sup>a</sup> Dalacin C [PF]

**■ CLINDAMYCIN****Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

3138E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	1	..	*22.43	23.88	<sup>a</sup> APO-Clindamycin [TX] <sup>a</sup> Clindamycin LU [XT] <sup>a</sup> Clindamylk [AF]	<sup>a</sup> Calindamin [RW] <sup>a</sup> CLINDAMYCIN-WGR [WG] <sup>a</sup> Dalacin C [PF]

**■ LINCOMYCIN****Note** Pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL vials and pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules are equivalent for the purposes of substitution.

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11366F <b>DP</b>	1	..	..	60.78	31.60	<sup>a</sup> LINCOMYCIN SXP [XN]

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11380Y <b>NP MW</b>	1	..	..	60.78	31.60	<sup>a</sup> LINCOMYCIN SXP [XN]

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2530E <b>NP MW</b>	1	..	..	60.78	31.60	<sup>a</sup> Lincocin [PF]

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5144R <b>DP</b>	1	..	..	60.78	31.60	<sup>a</sup> Lincocin [PF]

**AMINOGLYCOSIDE ANTIBACTERIALS***Other aminoglycosides***■ GENTAMICIN**

**Caution** If prescribed for sepsis (or suspected sepsis) by an authorised PBS prescriber who is not a medical practitioner, the decision to prescribe this benefit is to be shared with a medical practitioner.

**gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2824P <b>NP MW</b>	1	1	..	24.98	26.43	Pfizer Australia Pty Ltd [PF]

**■ TOBRAMYCIN****Restricted benefit**

Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

**tobramycin 500 mg/5 mL injection, 10 x 5 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9480Y <b>NP</b>	1	1	..	193.82	31.60	Tobra-Day [FF]

**■ TOBRAMYCIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****5520**

Proven Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5442K	1	2	..	372.45	31.60	<sup>a</sup> Tobo [GO] <sup>a</sup> Tobramycin WKT [JU]	<sup>a</sup> TOBRAMYCIN SUN [RA]

**■ TOBRAMYCIN****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**tobramycin 80 mg/2 mL injection, 5 x 2 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1356J <b>NP</b>	2	1	..	*39.91	31.60	Tobramycin Viartis [AL]

**tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8872Y <b>NP</b>	2	1	..	*48.43	31.60	Pfizer Australia Pty Ltd [PF]

## ■ TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**15040**

Proven *Pseudomonas aeruginosa* infection

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

### **tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

14006E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*736.45	31.60	<sup>a</sup> Tobr [GO]	<sup>a</sup> TOBRAMYCIN SUN [RA]
						<sup>a</sup> Tobramycin WKT [JU]	

## ■ TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**4456**

Proven *Pseudomonas aeruginosa* infection

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

### **Population criteria:**

- Patient must be 6 years of age or older.

### **tobramycin 28 mg powder for inhalation, 224 capsules**

10066T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2418.38	31.60	TOBI podhaler [GO]

## ■ TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**4513**

Proven *Pseudomonas aeruginosa* infection

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

### **Population criteria:**

- Patient must be 6 years of age or older.

### **tobramycin 28 mg powder for inhalation, 224 capsules**

10074F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2418.38	31.60	TOBI podhaler [GO]

## ■ TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**15036**

Proven *Pseudomonas aeruginosa* infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

13965B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4728.31	31.60	TOBI podhaler [GO]

**QUINOLONE ANTIBACTERIALS***Fluoroquinolones***■ CIPROFLOXACIN****Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.


**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**ciprofloxacin 500 mg tablet, 14**

1209P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	17.87	19.32	<sup>a</sup> APO-Ciprofloxacin [TX] <sup>a</sup> Ciprofloxacin Sandoz [SZ] <sup>a</sup> Ciprol 500 [RW]	<sup>a</sup> C-Flox 500 [AL] <sup>a</sup> CIPROFLOXACIN-WGR [WG] <sup>a</sup> NOUMED CIPROFLOXACIN [VO]

**ciprofloxacin 750 mg tablet, 14**

1210Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.85	20.30	<sup>a</sup> APO-Ciprofloxacin [TX] <sup>a</sup> Ciprofloxacin Sandoz [SZ] <sup>a</sup> Ciprol 750 [RW]	<sup>a</sup> C-Flox 750 [AL] <sup>a</sup> CIPROFLOXACIN-WGR [WG] <sup>a</sup> NOUMED CIPROFLOXACIN [VO]

**■ CIPROFLOXACIN****Authority required**

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

**Authority required**

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority required**

Infection

**Clinical criteria:**

- The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Gonorrhoea

**ciprofloxacin 250 mg tablet, 14**

1208N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.35	18.80	<sup>a</sup> APO-Ciprofloxacin [TX] <sup>a</sup> Ciprofloxacin Sandoz [SZ] <sup>a</sup> Ciprol 250 [RW]	<sup>a</sup> C-Flox 250 [AL] <sup>a</sup> CIPROFLOXACIN-WGR [WG]

**■ NORFLOXACIN****Authority required**

Acute bacterial enterocolitis

**Authority required**

Complicated urinary tract infection

**norfloxacin 400 mg tablet, 14**

3010K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.37	18.82	<sup>a</sup> APO-Norfloxacin [TX] <sup>a</sup> Roxin [RW]	<sup>a</sup> Nufloxib [AF]

## OTHER ANTIBACTERIALS

*Glycopeptide antibacterials*

## ■ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 1 g injection, 1 vial**

2269K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	19.91	21.36	Vancomycin Viatris [AL]

**vancomycin 500 mg injection, 1 vial**

3130R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*22.09	23.54	Vancomycin Viatris [AL]

## ■ VANCOMYCIN

**Restricted benefit**

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 1 g injection, 1 vial**

5083M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	19.91	21.36	Vancomycin Viatris [AL]

**vancomycin 500 mg injection, 1 vial**

3323X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*22.09	23.54	Vancomycin Viatris [AL]

## ■ VANCOMYCIN

**Restricted benefit**

Endophthalmitis

**vancomycin 1 g injection, 1 vial**

2270L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*32.82	31.60	Vancomycin Viatris [AL]

**vancomycin 500 mg injection, 1 vial**

3131T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*35.02	31.60	Vancomycin Viatris [AL]

## ■ VANCOMYCIN

**Restricted benefit**

Infection

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

**vancomycin 1 g injection, 1 vial**

14704X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
MW	3	..	..	*32.82	31.60	Vancomycin Viatris [AL]

**vancomycin 500 mg injection, 1 vial**

14696L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
MW	5	..	..	*35.02	31.60	Vancomycin Viatris [AL]

*Steroid antibacterials*

## ■ FUSIDATE

**Restricted benefit**

Serious staphylococcal infections

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

**sodium fusidate 250 mg tablet, 36**

2312Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	101.29	31.60	Fucidin [LO]

**■ FUSIDATE****Authority required (STREAMLINED)****6133**

Osteomyelitis

**Clinical criteria:**

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

**sodium fusidate 250 mg tablet, 36**

10782L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*192.91	31.60	Fucidin [LO]

*Imidazole derivatives***■ METRONIDAZOLE****metronidazole 500 mg suppository, 10**

1642K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	30.42	31.60	Flagyl [SW]

**metronidazole 500 mg suppository, 10**

5157K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	30.42	31.60	Flagyl [SW]

**metronidazole 200 mg tablet, 21**

1636D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	16.37	17.82	<sup>a</sup> Metrogyl 200 [XT]	<sup>a</sup> METRONIDAMED [DZ]

**metronidazole 200 mg tablet, 21**

3339R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.37	17.82	<sup>a</sup> Metrogyl 200 [XT]	<sup>a</sup> METRONIDAMED [DZ]

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

1630T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	±1	..	..	24.24	25.69	Flagyl S [SW]

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

3341W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	24.24	25.69	Flagyl S [SW]

**■ METRONIDAZOLE****Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

1621H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	17.14	18.59	<sup>a</sup> Metrogyl 400 [XT]	<sup>a</sup> METRONIDAMED [DZ]
			<sup>B</sup> 2.50	19.64	18.59	<sup>a</sup> Flagyl [SW]	

**■ METRONIDAZOLE****Restricted benefit**

Anaerobic infections

**metronidazole 400 mg tablet, 21**

5155H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	17.14	18.59	<sup>a</sup> Metrogyl 400 [XT]	<sup>a</sup> METRONIDAMED [DZ]
			<sup>B</sup> 2.50	19.64	18.59	<sup>a</sup> Flagyl [SW]	

*Nitrofurantoin derivatives***■ NITROFURANTOIN****Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.**nitrofurantoin 100 mg capsule, 30**

1693D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	27.45	28.90	<sup>a</sup> ARX-Nitrofurantoin [XT]	<sup>a</sup> Nitrofurantoin BNM [BZ]



**nitrofurantoin 50 mg capsule, 30**

1692C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	1	..	23.43	24.88	<sup>a</sup> ARX-Nitrofurantoin [XT]	<sup>a</sup> Nitrofurantoin BNM [BZ]

*Other antibacterials***■ METHENAMINE HIPPURATE****methenamine hippurate 1 g tablet, 100**

3124K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	31.76	31.60	<sup>a</sup> Hiprex [IL]	<sup>a</sup> Uramet [AS]

**■ METHENAMINE HIPPURATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**methenamine hippurate 1 g tablet, 100**

14005D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*50.07	31.60	<sup>a</sup> Hiprex [IL]	<sup>a</sup> Uramet [AS]

**■ ANTIMYCOTICS FOR SYSTEMIC USE****ANTIMYCOTICS FOR SYSTEMIC USE***Triazole and tetrazole derivatives***■ FLUCONAZOLE**

**Note** Not for use in vulvovaginal candida infections.

**Authority required (STREAMLINED)****15984**

Cryptococcal meningitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****15975**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****6023**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****6030**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****5989**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****16034**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**fluconazole 100 mg capsule, 28**

1472L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.86	27.31	<sup>a</sup> Dizole 100 [XT]	<sup>a</sup> Fluconazole Sandoz [SZ]
						<sup>a</sup> Ozole [RA]	
			<sup>B</sup> 13.00	38.86	27.31	<sup>a</sup> Diflucan [PF]	

**fluconazole 200 mg capsule, 28**

1475P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.62	31.60	<sup>a</sup> APO-Fluconazole [TX]	<sup>a</sup> Dizole 200 [XT]
						<sup>a</sup> Fluconazole APOTEX [GX]	<sup>a</sup> Fluconazole Sandoz [SZ]
						<sup>a</sup> FLUCONAZOLE-WGR [WG]	<sup>a</sup> Fluzole 200 [RW]
						<sup>a</sup> Ozole [RA]	
			<sup>B</sup> 19.50	57.12	31.60	<sup>a</sup> Diflucan [PF]	

**fluconazole 50 mg capsule, 28**

1471K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.84	21.29	<sup>a</sup> Dizole 50 [XT]	<sup>a</sup> Fluconazole Sandoz [SZ]
						<sup>a</sup> Ozole [RA]	
			<sup>B</sup> 9.25	29.09	21.29	<sup>a</sup> Diflucan [PF]	

**■ FLUCONAZOLE**

**Note** Not for use in vulvovaginal candida infections.

**Authority required (STREAMLINED)****16141**

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16148**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****6031**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)****6032**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)****6046**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)****16114**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**fluconazole 50 mg/5 mL powder for oral liquid, 35 mL**

5446P

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	#70.16	31.60	Diflucan [PF]

NP

**■ ITRACONAZOLE****Note** Not for use in vulvovaginal candida infections.**Note** Not for use in superficial mycoses**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules. The recommended dose for Lozanoc is therefore half the recommended dose for conventional itraconazole capsules. Lozanoc 50 mg capsules and conventional itraconazole 100 mg capsules are not interchangeable.**Authority required (STREAMLINED)****16119**

Systemic aspergillosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****15978**

Systemic sporotrichosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16035**

Systemic histoplasmosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16099**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16101**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)****16073**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required (STREAMLINED)**

**16102**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**itraconazole 100 mg capsule, 60**

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	118.22	31.60	<sup>a</sup> Itracap [AF]	<sup>a</sup> ITRANOX [RW]

**itraconazole 50 mg capsule, 60**

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	118.22	31.60	Lozanoc [YN]	

**■ POSACONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Authority required**

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required**

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

**Authority required**

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**posaconazole 100 mg modified release tablet, 24**

10460M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	126.74	31.60	<sup>a</sup> Pharmacor Posaconazole [CR] <sup>a</sup> POSACONAZOLE DR.REDDY'S [RZ] <sup>a</sup> Posaconazole Sandoz [SZ]	<sup>a</sup> Posaconazole ARX [XT] <sup>a</sup> Posaconazole Juno [JU] <sup>a</sup> POSACONAZOLE-WGR [WG]

## ■ VORICONAZOLE

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

### Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

### Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### voriconazole 40 mg/mL powder for oral liquid, 70 mL

10168E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#507.39	31.60	Vfend [PF]

### voriconazole 200 mg tablet, 56

10198R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	198.73	31.60	<sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Vttack [AF]

### voriconazole 50 mg tablet, 56

10173K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	58.76	31.60	<sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Vttack [AF]

## ■ VORICONAZOLE

### Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

### Clinical criteria:

- Patient must be immunocompromised.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

### Clinical criteria:

- The condition must be caused by *Scedosporium* species; OR
- The condition must be caused by *Fusarium* species.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### Authority required

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

### Clinical criteria:

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**voriconazole 200 mg tablet, 56**

9364W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	198.73	31.60	<sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Vttack [AF]

**voriconazole 50 mg tablet, 56**

9363T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	58.76	31.60	<sup>a</sup> Voriconazole Sandoz [SZ] <sup>a</sup> Vzole [RW]	<sup>a</sup> Vttack [AF]

▪ **VORICONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by *Scedosporium* species; OR
- The condition must be caused by *Fusarium* species.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required**

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

9452L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#507.39	31.60	Vfend [PF]

## ■ ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

#### Antibiotics

#### ■ RIFAMPICIN

##### Authority required

Mycobacterium ulcerans infection (Buruli ulcer)

##### Clinical criteria:

- The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer.

##### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

#### rifampicin 150 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12200D	12	..	..	*232.47	31.60	Rimycin 150 [AF]

#### rifampicin 150 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12190N	1	..	..	195.19	31.60	Rimycin 150 [AF]

#### rifampicin 300 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12189M	12	..	..	*110.79	31.60	Rimycin 300 [AF]

#### rifampicin 300 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12215X	1	..	..	94.53	31.60	Rimycin 300 [AF]

#### Hydrazides

#### ■ ISONIAZID

##### Restricted benefit

For prescribing by certain health practitioners

##### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

#### isoniazid 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1554T	1	2	..	21.73	23.18	Arrow Pharma Pty Ltd [RW]

### DRUGS FOR TREATMENT OF LEPROSY

#### Drugs for treatment of leprosy

#### ■ DAPSONE

#### dapsone 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1272Y	1	1	..	401.14	31.60	<sup>a</sup> DAPSOMED [DZ]	<sup>a</sup> Link Medical Products Pty Ltd [LM]

#### dapsone 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8801F	1	1	..	328.45	31.60	Link Medical Products Pty Ltd [LM]

#### ■ RIFAMPICIN

##### Authority required

Leprosy

##### Population criteria:

- Patient must be an adult.

##### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

## ANTIINFECTIVES FOR SYSTEMIC USE

### rifampicin 150 mg capsule, 100

1982H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	195.19	31.60	Rimycin 150 [AF]

### rifampicin 300 mg capsule, 100

1983J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	94.53	31.60	Rimycin 300 [AF]

## ■ RIFAMPICIN

### Restricted benefit

Meningococcal disease

### Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### Restricted benefit

Haemophilus influenzae type B

### Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### rifampicin 150 mg capsule, 10

1981G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.24	31.60	Rimycin 150 [AF]

### rifampicin 300 mg capsule, 10

1984K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.57	23.02	Rimycin 300 [AF]

### rifampicin 100 mg/5 mL oral liquid, 60 mL

8025J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	26.60	28.05	Rifadin [SW]

## ■ ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

## ■ ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

### Authority required (STREAMLINED)

**5942**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### aciclovir 200 mg tablet, 90

1007B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	5	..	31.65	31.60	<sup>a</sup> Aciclovir APOTEX [TY] <sup>a</sup> Aciclovir Sandoz [HX] <sup>a</sup> APO-Aciclovir [TX]	<sup>a</sup> Aciclovir GH [GQ] <sup>a</sup> ACICLOVIR-WGR [WG] <sup>a</sup> ARX-ACICLOVIR [XT]

## ■ ACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

### Authority required (STREAMLINED)

**5967**

Herpes zoster



**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)****5959**

Herpes zoster ophthalmicus

**aciclovir 800 mg tablet, 35**

1052J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	35.48	31.60	<sup>a</sup> Aciclovir APOTEX [TY] <sup>a</sup> ACICLOVIR-WGR [WG] <sup>a</sup> ARX-ACICLOVIR [XT]	<sup>a</sup> Aciclovir Sandoz [HX] <sup>a</sup> APO-Aciclovir [TX]

**■ ACICLOVIR**

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****5936**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 25**

1003T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*23.57	25.02	<sup>a</sup> Aciclovir Sandoz [HX]

**aciclovir 200 mg tablet, 50**

1555W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	23.57	25.02	<sup>a</sup> Aciclovir APOTEX [TY]	<sup>a</sup> APO-Aciclovir [TX]

**■ FAMCICLOVIR**

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5937**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 20**

2274Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	32.11	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Famvir [IX]	<sup>a</sup> FAMCICLOVIR-WGR [WG] <sup>a</sup> Favic 250 [RW]

**■ FAMCICLOVIR**

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5937**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 125 mg tablet, 40**

8092X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	32.11	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Favic 125 [RW]	<sup>a</sup> Famvir [IX]

**■ FAMCICLOVIR**

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5971**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 250 mg tablet, 56**

8217L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	65.69	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> FAMCICLOVIR-WGR [WG] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Ezovir [XT] <sup>a</sup> Famvir [IX]

**■ FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)****5951**

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 250 mg tablet, 21**

8002E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	33.05	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> FAMCICLOVIR-WGR [WG] <sup>a</sup> Favic 250 [RW]	<sup>a</sup> Ezovir [XT] <sup>a</sup> Famvir [IX]

**■ FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note** No applications for repeats will be authorised.

**Authority required (STREAMLINED)****5943**

Herpes zoster

**Clinical criteria:**

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 500 mg tablet, 30**

8897G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	41.46	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> Famvir [IX]	<sup>a</sup> FAMCICLOVIR-WGR [WG] <sup>a</sup> Favic 500 [RW]

**■ FAMCICLOVIR**

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority required (STREAMLINED)****5954**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

**Clinical criteria:**

- Patient must be immunocompromised.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)****5947**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)****5948**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

**5949**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 500 mg tablet, 56**

8896F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.73	31.60	<sup>a</sup> APO-Famciclovir [TX] <sup>a</sup> FAMCICLOVIR-WGR [WG] <sup>a</sup> Favic 500 [RW]	<sup>a</sup> Ezovir [XT] <sup>a</sup> Famvir [IX]

▪ **MOLNUPIRAVIR**

**Note** Details of the Liverpool COVID-19 Drug interaction checker can be found at: <https://www.covid19-druginteractions.org/checker>

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16190**

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**16191**

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

- Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
- Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
- Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

- a. Chemotherapy or whole body radiotherapy,
- b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
- c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
- d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR
3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR
4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR
5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

#### **Authority required (STREAMLINED)**

#### **16200**

SARS-CoV-2 infection

#### **Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

#### **Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.
- For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

**Authority required (STREAMLINED)**

**16201**

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.
- For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

**molnupiravir 200 mg capsule, 40**

12910L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1102.71	31.60	Lagevrio [MK]

▪ **VALACICLOVIR**

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**5940**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

5480K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	5	..	26.36	27.81	<sup>a</sup> APX-Valaciclovir [TY]	<sup>a</sup> Shilova 500 [ZS]
						<sup>a</sup> Valtrex [AF]	<sup>a</sup> Valaciclovir APOTEX [GX]
						<sup>a</sup> Valaciclovir RBX [RA]	<sup>a</sup> Valaciclovir Sandoz [SZ]
						<sup>a</sup> Valaciclovir SZ [HX]	<sup>a</sup> VALACICLOVIR-WGR [WG]
						<sup>a</sup> Zelitrex [RF]	
			<sup>b</sup> 2.43	28.79	27.81	<sup>a</sup> Valtrex [RW]	

▪ **VALACICLOVIR**

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)****5961**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 30**

8134D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.36	27.81	<sup>a</sup> APX-Valaciclovir [TY]	<sup>a</sup> Shilova 500 [ZS]
						<sup>a</sup> Vaclovir [AF]	<sup>a</sup> Valaciclovir APOTEX [GX]
						<sup>a</sup> Valaciclovir RBX [RA]	<sup>a</sup> Valaciclovir Sandoz [SZ]
						<sup>a</sup> Valaciclovir SZ [HX]	<sup>a</sup> VALACICLOVIR-WGR [WG]
						<sup>a</sup> Zelitrex [RF]	
			<sup>b</sup> 2.43	28.79	27.81	<sup>a</sup> Valtrex [RW]	

**■ VALACICLOVIR****Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****5960**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**valaciclovir 500 mg tablet, 10**

8133C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*22.07	23.52	<sup>a</sup> APX-Valaciclovir [TY]	<sup>a</sup> Vaclovir [AF]
						<sup>a</sup> Valaciclovir APOTEX [GX]	<sup>a</sup> Valaciclovir Sandoz [SZ]
						<sup>a</sup> VALACICLOVIR-WGR [WG]	<sup>a</sup> Zelitrex [RF]
			<sup>b</sup> 5.40	*27.47	23.52	<sup>a</sup> Valtrex [RW]	

**■ VALACICLOVIR****Note** This drug is only effective if commenced within 72 hours of onset of rash.**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.**Note** No applications for repeats will be authorised.**Authority required (STREAMLINED)****5962**

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Authority required (STREAMLINED)****5968**

Herpes zoster ophthalmicus

**valaciclovir 500 mg tablet, 42**

8064K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	31.52	31.60	<sup>a</sup> APX-Valaciclovir [TY]	<sup>a</sup> Vaclovir [AF]
						<sup>a</sup> Valaciclovir APOTEX [GX]	<sup>a</sup> Valaciclovir RBX [RA]
						<sup>a</sup> Valaciclovir Sandoz [SZ]	<sup>a</sup> VALACICLOVIR-WGR [WG]
						<sup>a</sup> Zelitrex [RF]	
			<sup>b</sup> 2.43	33.95	31.60	<sup>a</sup> Valtrex [RW]	

**Protease inhibitors****■ NIRMATRELVIR (&) RITONAVIR****Caution** Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required (STREAMLINED)****16155**

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**

- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

**16223**

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority required (STREAMLINED)**

**16192**

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

## **Authority required (STREAMLINED)**

**16156**

SARS-CoV-2 infection

### **Clinical criteria:**

- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

### **Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m<sup>2</sup>),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>



**nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6**

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	1115.31	31.60	Paxlovid [PF]

*Antivirals for treatment of HCV infections***■ GLECAPREVIR + PIBRENTASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11344C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17009.27	31.60	Maviret [VE]

**■ GLECAPREVIR + PIBRENTASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11353M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17009.27	31.60	Maviret [VE]

**■ GLECAPREVIR + PIBRENTASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11354N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17009.27	31.60	Maviret [VE]

**■ SOFOSBUVIR + VELPATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

11147Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12037.60	31.60	Epclusa [GI]

**▪ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 12 weeks.
- The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28**

11658N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12037.60	31.60	Vosevi [GI]

*Antivirals for treatment of HIV infections, combinations***▪ TENOFOVIR DISOPROXIL + EMTRICITABINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Note** In the case of a shortage, pharmaceutical benefits that have the brand Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) can be substituted for pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet.

**Restricted benefit**

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

11276L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	34.96	31.60	<sup>a</sup> CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR]	<sup>a</sup> TENOFOVIR/EMTRICITABINE 300/200 ARX [XT]

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

14636H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	105.70	31.60	<sup>a</sup> Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) [KQ]

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

11296M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	<sup>a</sup> Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL]

**tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30**

12542D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	31.25	31.60	<sup>a</sup> Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

**▪ VACCINES****BACTERIAL VACCINES***Tetanus vaccines***▪ DIPHTHERIA + TETANUS VACCINE**

**Note** For immunisation of adults and children aged greater than or equal to 8 years.

**diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes**

8783G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	94.45	31.60	ADT Booster [CS]

■ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**■ **ANTINEOPLASTIC AGENTS****ALKYLATING AGENTS***Nitrogen mustard analogues*■ **CHLORAMBUCIL****chlorambucil 2 mg tablet, 25**

1163F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*136.71	31.60	Leukeran [AS]

■ **CHLORMETHINE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Mycosis fungoides cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be any of: (i) Stage IA, (ii) IIA, (iii) IB mycosis fungoides cutaneous T-cell lymphoma, **AND**
- The condition must have been confirmed through a diagnostic lesion biopsy from an Approved Pathology Authority, **AND**
- The condition must cover either of which: (i) no more than 10% of the patient's body surface area, (ii) no more than 25% of the patient's body surface area, **AND**
- Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist, **AND**
- The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script; OR
- The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script.

**Population criteria:**

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**Authority required**

Mycosis fungoides cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist, **AND**
- The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script; OR
- The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script.

**chlormethine 0.016% (160 microgram/g) gel, 60 g**

14658L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*3406.79	31.60	Ledaga [JZ]

■ **CYCLOPHOSPHAMIDE****cyclophosphamide 50 mg tablet, 50**

1266P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	157.09	31.60	Cyclonex [GH]

■ **MELPHALAN****melfhalan 2 mg tablet, 25**

2547C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	65.41	31.60	Alkeran [AS]

*Alkyl sulfonates*

■ **BUSULFAN****busulfan 2 mg tablet, 100**

1128J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	..	..	79.49	31.60	Myleran [AS]	

*Nitrosoureas*■ **CARMUSTINE**

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

**Restricted benefit**

Glioblastoma multiforme

**Clinical criteria:**

- The condition must be suspected or confirmed at the time of initial surgery.

**carmustine 7.7 mg implant, 8**

8898H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	±1	..	..	11150.92	31.60	Gliadel [EI]	

*Other alkylating agents*■ **TEMOZOLOMIDE****temozolomide 180 mg capsule, 5**

2438H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	121.02	31.60	<sup>a</sup> APO-Temozolomide [TX]	<sup>a</sup> Temozolomide Juno [JX]

**temozolomide 100 mg capsule, 5**

8380C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	77.65	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK]	<sup>a</sup> Temizole 100 [AL] <sup>a</sup> Temozolomide Juno [JX]

**temozolomide 140 mg capsule, 5**

9362R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	101.98	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK]	<sup>a</sup> Temizole 140 [AL] <sup>a</sup> Temozolomide Juno [JX]

**temozolomide 20 mg capsule, 5**

8379B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	28.44	29.89	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temozolomide Juno [JX]	<sup>a</sup> Temizole 20 [AL]

**temozolomide 250 mg capsule, 5**

8381D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	168.60	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temozolomide Juno [JX]	<sup>a</sup> Temizole 250 [AL]

**temozolomide 5 mg capsule, 5**

8378Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	18.56	20.01	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temozolomide Juno [JX]	<sup>a</sup> Temizole 5 [AL]

■ **TEMOZOLOMIDE**

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Glioblastoma multiforme

**Treatment criteria:**

- Patient must be undergoing concomitant radiotherapy.

**temozolomide 180 mg capsule, 5**

10062N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*346.14	31.60	<sup>a</sup> APO-Temozolomide [TX]	<sup>a</sup> Temozolomide Juno [JX]

**temozolomide 100 mg capsule, 5**

8821G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*210.66	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK]	<sup>a</sup> Temizole 100 [AL] <sup>a</sup> Temozolomide Juno [JX]

**temozolomide 140 mg capsule, 5**

9361Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*287.31	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temodal [MK]	<sup>a</sup> Temizole 140 [AL] <sup>a</sup> Temozolomide Juno [JX]

**temozolomide 20 mg capsule, 5**

8820F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*58.41	31.60	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temozolomide Juno [JX]	<sup>a</sup> Temizole 20 [AL]

**temozolomide 5 mg capsule, 5**

8819E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*28.77	30.22	<sup>a</sup> APO-Temozolomide [TX] <sup>a</sup> Temozolomide Juno [JX]	<sup>a</sup> Temizole 5 [AL]

**ANTIMETABOLITES**

*Folic acid analogues*

▪ **METHOTREXATE**

**methotrexate 5 mg/2 mL injection, 5 x 2 mL vials**

2396D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	42.31	31.60	DBL Methotrexate [PF]

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

2395C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	40.88	31.60	DBL Methotrexate [PF]

**methotrexate 10 mg tablet, 15**

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	25.56	27.01	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

**methotrexate 2.5 mg tablet, 30**

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.29	20.74	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

**methotrexate 10 mg tablet, 10**

14643Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.52	22.97	<sup>a</sup> Chexate [OX]	<sup>a</sup> Methoblastin [PF]

▪ **METHOTREXATE**

Restricted benefit

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.78	31.60	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

▪ **METHOTREXATE**

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

13882P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*68.31	31.60	DBL Methotrexate [PF]

*Purine analogues*

▪ **FLUDARABINE**

**fludarabine phosphate 10 mg tablet, 20**

9184J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	938.84	31.60	Fludara [GZ]

▪ **MERCAPTOPURINE**

**mercaptopurine monohydrate 20 mg/mL oral liquid, 100 mL**

10214N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	381.68	31.60	Allmercap [LM]

**mercaptopurine monohydrate 50 mg tablet, 25**

1598D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*169.23	31.60	<sup>a</sup> MERCAPTOPURINE-LINK [LM]

<sup>B</sup>7.44    \*176.67    31.60    <sup>a</sup> Purinethol [AS]

## ■ TIOGUANINE

### tioguanine 40 mg tablet, 25

1233X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	194.76	31.60	Lanvis [AS]

### *Pyrimidine analogues*

## ■ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.  
Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

### azacitidine 200 mg tablet, 7

13623B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*13390.37	31.60	Onureg [BQ]

## ■ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Acute Myeloid Leukaemia

Treatment Phase: Dose escalation therapy - Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail:

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.

All reports must be documented in the patient's medical records.

### azacitidine 300 mg tablet, 7

13624C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*20004.24	31.60	Onureg [BQ]

## ■ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Initial treatment

#### Clinical criteria:

- Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy, **AND**
- Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation, **AND**
- Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk, **AND**
- Patient must not have undergone a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than  $1.0 \times 10^9/L$  and platelet count greater than or equal to  $100 \times 10^9/L$ .

A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than  $1.0 \times 10^9/L$  or platelet count less than  $100 \times 10^9/L$ .

#### Authority required

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

### azacitidine 300 mg tablet, 7

13619T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*13372.33	31.60	Onureg [BQ]

## ■ CAPECITABINE

### capecitabine 500 mg tablet, 120

8362D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	49.65	31.60	<sup>a</sup> Capecitabine Alphapharm [AF]	<sup>a</sup> Capecitabine Sandoz [SZ]
						<sup>a</sup> Xelabine [AL]	

## ■ DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**13258**

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13081L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4862.60	31.60	Inqovi 35/100 [TJ]

**▪ DECITABINE + CEDAZURIDINE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333. Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
PBS Authorities  
GPO Box 9826  
[Your capital city]

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following reports must be documented in the patient's medical records:

- (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) full blood examination report

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13133F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4862.60	31.60	Inqovi 35/100 [TJ]

**▪ DECITABINE + CEDAZURIDINE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**



- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

- (a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
- (b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- (c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- (d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
- (e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- (a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- (b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The following information must be provided by the prescriber at the time of application:

- (a) The patient's International Prognostic Scoring System (IPSS) score.

The following reports must be documented in the patient's medical records:

- (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (b) full blood examination report; and
- (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The following reports must be documented in the patient's medical records:

- (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (b) full blood examination report.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13087T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4862.60	31.60	Inqovi 35/100 [TJ]

▪ **DECITABINE + CEDAZURIDINE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have progressive disease.
- Up to 6 cycles will be authorised.

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have progressive disease.
- Up to 6 cycles will be authorised.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13107W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4862.60	31.60	Inqovi 35/100 [TJ]

**TRIFLURIDINE + TIPIRACIL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**10309**

Metastatic colorectal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; OR
- Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

**Authority required (STREAMLINED)**
**8183**

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

11507P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*2284.02	31.60	Lonsurf 15/6.14 [SE]

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

11524M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*3934.07	31.60	Lonsurf 20/8.19 [SE]

**TRIFLURIDINE + TIPIRACIL**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**10252**

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

**Authority required (STREAMLINED)**
**10310**

Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

12056M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*2284.02	31.60	Lonsurf 15/6.14 [SE]

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

12033H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*3934.07	31.60	Lonsurf 20/8.19 [SE]

**PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS**

*Vinca alkaloids and analogues*

■ **VINORELBINE**

**Authority required**

Advanced breast cancer

**Clinical criteria:**

- Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

**vinorelbine 20 mg capsule, 1**

9009E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	20	2	..	*1032.47	31.60	<sup>a</sup> Navelbine [FB]	<sup>a</sup> Velabine [XT]

**vinorelbine 30 mg capsule, 1**

9010F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	16	2	..	*1232.35	31.60	<sup>a</sup> Navelbine [FB]	<sup>a</sup> Velabine [XT]

*Podophyllotoxin derivatives*

■ **ETOPOSIDE**

**etoposide 100 mg capsule, 10**

1389D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	393.09	31.60	Vepesid [LM]

**etoposide 50 mg capsule, 20**

1396L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	450.01	31.60	Vepesid [LM]

**PROTEIN KINASE INHIBITORS**

*BCR-ABL tyrosine kinase inhibitors*

■ **ASCIMINIB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13923**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**asciminib 40 mg tablet, 60**

13259W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6131.79	31.60	Scemblix [NV]

■ **ASCIMINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**13923**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

#### **asciminib 20 mg tablet, 60**

13268H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6175.10	31.60	Scemblix [NV]

### ■ ASCIMINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients without T315I mutation

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be in the blast phase, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors; OR
- Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors; OR
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

- (i) failure to achieve a haematological response after a minimum of 3 months therapy; or
- (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or
- (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

#### asciminib 20 mg tablet, 60

13248G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6175.10	31.60	Scemblix [NV]

#### asciminib 40 mg tablet, 60

13264D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6131.79	31.60	Scemblix [NV]

### ■ ASCIMINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients with T315I mutation

#### **Clinical criteria:**

- The condition must not be in the blast phase, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of a tyrosine kinase inhibitor is defined as:

1. Lack of response defined as either:

- (i) failure to achieve a haematological response after a minimum of 3 months therapy; or
- (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or
- (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR

4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or
- (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and
- (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and
- (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Tyrosine Kinase Inhibitors (TKI) are defined as either (i) imatinib, (ii) dasatinib, (iii) nilotinib, (iv) ponatinib

#### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing Treatment for patients with T315I mutation

#### Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or
- (ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

#### asciminib 40 mg tablet, 60

13260X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*30225.12	31.60	Scemblix [NV]

#### ■ DASATINIB

##### Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

##### 1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only

be approved for PBS-subsidised treatment with one third-line agent.

## 2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

## 3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

## 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

## 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## Authority required (STREAMLINED)

### 12522

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

### Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

## dasatinib 100 mg tablet, 30

12842X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

## dasatinib 20 mg tablet, 60

12888H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

## dasatinib 50 mg tablet, 60

12857Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

## dasatinib 70 mg tablet, 60

12866E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA]

## ■ DASATINIB

### **Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

#### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

#### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

#### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required (STREAMLINED)**

**12565**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.



**dasatinib 100 mg tablet, 30**

12889J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 20 mg tablet, 60**

12869H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 50 mg tablet, 60**

12843Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 70 mg tablet, 60**

12890K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**■ DASATINIB**
**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

**1. Initial third-line treatment**

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

**2. Continuing treatment for third-line treatment**

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

**3. Authority approval requirements**

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph

positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

#### **Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of nilotinib is defined as:

(i) Lack of response to second line nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or
- failure to achieve any cytogenetic response after a minimum of 6 months therapy with nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with nilotinib; OR

ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
- (3) Peripheral basophils greater than or equal to 20%; or
- (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
- (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
- (2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

#### **dasatinib 100 mg tablet, 30**

12902C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 20 mg tablet, 60**

12849G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 50 mg tablet, 60**

12865D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 70 mg tablet, 60**

12886F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**■ DASATINIB**
**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

**1. Initial second-line treatment**

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

**2. Continuing treatment for second-line treatment**

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

**3. Authority approval requirements**

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously

demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

**12530**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

#### Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

#### dasatinib 100 mg tablet, 30

12859T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

#### dasatinib 20 mg tablet, 60

12850H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

#### dasatinib 50 mg tablet, 60

12860W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

#### dasatinib 70 mg tablet, 60

12903D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

### ■ DASATINIB

#### **Note** TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

##### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

##### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

### Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### dasatinib 100 mg tablet, 30

1416M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

### dasatinib 20 mg tablet, 60

1354G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA]

<sup>a</sup> DASATINIB-TEVA [TB]

<sup>a</sup> Dasatinib Viatris [AL]

<sup>a</sup> Sprycel [BQ]

**dasatinib 50 mg tablet, 60**

1381Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 70 mg tablet, 60**

1415L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**■ DASATINIB**
**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

**1. Initial second-line treatment**

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

**2. Continuing treatment for second-line treatment**

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

**3. Authority approval requirements**

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

#### Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase; OR
- The condition must be in the blast phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or
- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
- (3) Peripheral basophils greater than or equal to 20%; or
- (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
- (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);

Blast crisis is defined as either:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
- (2) Extramedullary involvement other than spleen and liver; OR
- (v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or nilotinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

#### dasatinib 100 mg tablet, 30

9342Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

#### dasatinib 20 mg tablet, 60

2478K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT]	<sup>a</sup> Dasatinib Dr.Reddy's [RI]

<sup>a</sup> Dasatinib Sandoz [SZ]  
<sup>a</sup> DASATINIB-TEVA [TB]  
<sup>a</sup> Sprycel [BQ]

<sup>a</sup> Dasatinib SUN [RA]  
<sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 50 mg tablet, 60**

2482P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 70 mg tablet, 60**

2485T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**■ DASATINIB**

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable.

Failure of treatment is defined as either:

- (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;
  - (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;
  - (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.
- Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib, **AND**
- The condition must not have progressed.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; OR
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, confirm that:

- 1) The condition is expressing the Philadelphia chromosome,
- 2) Measurable residual disease (MRD) is present,
- 3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,
- 4) MRD has been confirmed within the preceding 6 months of this authority application,
- 5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,
- 6) Allogeneic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**dasatinib 100 mg tablet, 30**

9343R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT]	<sup>a</sup> Dasatinib Dr.Reddy's [RI]

<sup>a</sup> Dasatinib Sandoz [SZ]  
<sup>a</sup> DASATINIB-TEVA [TB]  
<sup>a</sup> Sprycel [BQ]

<sup>a</sup> Dasatinib SUN [RA]  
<sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 20 mg tablet, 60**

9125G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	706.96	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 50 mg tablet, 60**

9126H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1135.33	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**dasatinib 70 mg tablet, 60**

9127J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1390.06	31.60	<sup>a</sup> Dasatinib ARX [XT] <sup>a</sup> Dasatinib Sandoz [SZ] <sup>a</sup> DASATINIB-TEVA [TB] <sup>a</sup> Sprycel [BQ]	<sup>a</sup> Dasatinib Dr.Reddy's [RI] <sup>a</sup> Dasatinib SUN [RA] <sup>a</sup> Dasatinib Viatris [AL]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

10918P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

9176Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

### imatinib 400 mg capsule, 30

10921T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9179D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

### imatinib 400 mg capsule, 30

10925B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9175X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

### imatinib 400 mg capsule, 30

10933K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9173T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

#### imatinib 400 mg capsule, 30

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

#### imatinib 400 mg tablet, 30

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

### ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

#### imatinib 100 mg capsule, 60

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

#### imatinib 100 mg tablet, 60

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

### ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

10941W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

9174W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**

- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

10942X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

9172R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**9209**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

11776T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11753N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****9243**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

11756R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11765F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****9243**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

11757T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11769K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****9296**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not exceed a maximum dose of 400 mg per day.
- A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

11763D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11758W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**9206**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

11777W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11762C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**9209**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

11764E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11786H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR]	<sup>a</sup> Glivec [NV]

<sup>a</sup> Imanib [AF]<sup>a</sup> IMATINIB RBX [RA]<sup>a</sup> Imatinib Sandoz [SZ]<sup>a</sup> Imatinib-Teva [TB]**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****9296**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

11770L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11781C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****9206**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

11779Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11785G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****9278**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**



- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**imatinib 100 mg capsule, 60**

12710Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11784F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****9278**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**imatinib 400 mg capsule, 30**

12711B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11788K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 400 mg capsule, 30**

12681K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

5444M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 100 mg capsule, 60**

12759M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

5443L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****13132**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 600 mg tablet, 30**

12919Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

## ■ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**9209**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

### **imatinib 600 mg tablet, 30**

12923E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.09	31.60	Imatab [JU]

## ■ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

### **imatinib 600 mg tablet, 30**

12927J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.09	31.60	Imatab [JU]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

#### **1. Initial First-line treatment**

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

#### **2. Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at

any time failed to meet the response criteria whilst on that TKI agent.

### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

### Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### imatinib 100 mg capsule, 60

10915L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

### imatinib 100 mg tablet, 60

9113P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

**1. Initial First-line treatment**

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

**2. Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

**3. Authority approval requirements**

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### imatinib 400 mg capsule, 30

10916M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9114Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Note** TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

#### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

#### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

#### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by

at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**

**12536**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

11772N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11752M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**16249**

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; OR
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

- 1) The condition is expressing the Philadelphia chromosome,
- 2) Measurable residual disease (MRD) is present,
- 3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,
- 4) MRD has been confirmed within the preceding months of this authority application,
- 5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,
- 6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 400 mg capsule, 30**

11771M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11789L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

**1. Initial First-line treatment**

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

**2. Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

**3. Authority approval requirements**

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**
**12536**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR



- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

#### imatinib 100 mg capsule, 60

11782D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

#### imatinib 100 mg tablet, 60

11775R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

### ■ IMATINIB

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

#### Authority required (STREAMLINED)

##### 13132

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

#### imatinib 400 mg capsule, 30

12723P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

#### imatinib 400 mg tablet, 30

11778X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

### ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

##### 16249

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; OR
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

- 1) The condition is expressing the Philadelphia chromosome,
- 2) Measurable residual disease (MRD) is present,
- 3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,
- 4) MRD has been confirmed within the preceding months of this authority application,
- 5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,
- 6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 100 mg capsule, 60**

11783E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11780B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****13132**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 100 mg capsule, 60**

12722N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11787J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

12709X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT]	<sup>a</sup> Imatinib-APOTEX [TX]
						<sup>a</sup> IMATINIB-DRLA [RZ]	

**imatinib 100 mg tablet, 60**

9111M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR]	<sup>a</sup> Glivec [NV]
						<sup>a</sup> Imanib [AF]	<sup>a</sup> IMATINIB RBX [RA]
						<sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Imatinib-Teva [TB]

▪ **IMATINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

12754G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

9112N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The condition must have not achieved a response with this drug at a dose of 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records. Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12926H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

**■ IMATINIB**

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report

documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

### imatinib 400 mg capsule, 30

10917N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9124F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

### Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

### Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### imatinib 100 mg capsule, 60

10920R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

### imatinib 100 mg tablet, 60

9115R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

#### Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

### imatinib 100 mg capsule, 60

10924Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

### imatinib 100 mg tablet, 60

9123E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

#### Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition. Accelerated phase is defined by the presence of 1 or more of the following:
  - Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
  - Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
  - Peripheral basophils greater than or equal to 20%; or
  - Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
  - Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).
- A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.
- The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

- Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
- Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

10935M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

9116T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

■ **IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**12542**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**Authority required (STREAMLINED)****12525**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**imatinib 400 mg capsule, 30**

11870R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

**imatinib 400 mg tablet, 30**

11878E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	289.69	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****12542**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**Authority required (STREAMLINED)****12525**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

**imatinib 100 mg capsule, 60**

11875B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> ARX-IMATINIB [XT] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Imatinib-APOTEX [TX]

**imatinib 100 mg tablet, 60**

11880G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	149.09	31.60	<sup>a</sup> Gilmat [CR] <sup>a</sup> Imanib [AF] <sup>a</sup> Imatinib Sandoz [SZ]	<sup>a</sup> Glivec [NV] <sup>a</sup> IMATINIB RBX [RA] <sup>a</sup> Imatinib-Teva [TB]

**■ IMATINIB**

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Acute lymphoblastic leukaemia



Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12911M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

■ **IMATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

**1. Initial First-line treatment**

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

**2. Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

**3. Authority approval requirements**

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required (STREAMLINED)**

**12536**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12912N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.09	31.60	Imatab [JU]

**■ IMATINIB**

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
**16249**

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; OR
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

- 1) The condition is expressing the Philadelphia chromosome,
- 2) Measurable residual disease (MRD) is present,
- 3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,
- 4) MRD has been confirmed within the preceding months of this authority application,
- 5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,
- 6) Allogeneic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 600 mg tablet, 30**

12920B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

**■ IMATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

12924F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

■ **IMATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**12542**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

#### Authority required (STREAMLINED)

**12525**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR).

#### imatinib 600 mg tablet, 30

12928K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.09	31.60	Imatab [JU]

### ■ IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Note** TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

##### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

##### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

##### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

##### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

##### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by

at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

#### Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

#### Clinical criteria:

- The condition must be a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

#### imatinib 600 mg tablet, 30

12935T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.09	31.60	Imatab [JU]

#### ■ NILOTINIB

##### Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

##### 1. Initial second-line treatment

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

##### 2. Continuing treatment for second-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

## 3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

## 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

## 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)****12563**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - second-line therapy

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12858R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3780.40	31.60	Tasigna [NV]

■ **NILOTINIB****Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

## 1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

## 2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

## 3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required (STREAMLINED)

**12522**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - third-line therapy

#### Clinical criteria:

- Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; **OR**
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

### nilotinib 200 mg capsule, 120

12867F	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3780.40	31.60	Tasigna [NV]

## ■ NILOTINIB

### Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

#### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

#### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

#### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted

and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

##### **12572**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment - first-line therapy

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

#### **nilotinib 150 mg capsule, 120**

12868G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2893.12	31.60	Tasigna [NV]

### ■ NILOTINIB

#### **Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

##### 1. Initial First-line treatment

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

##### 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

##### 3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR



indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**12549**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy

#### **Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; **OR**
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

#### **nilotinib 200 mg capsule, 120**

12885E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3780.40	31.60	Tasigna [NV]

### ■ NILOTINIB

#### **Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - THIRD-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the third-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised third-line treatment of CML if they have experienced treatment failure in the second-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line or second-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the third-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the third-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for third-line treatment of CML.

#### 1. Initial third-line treatment

Third-line treatment with a TKI can only be approved when imatinib has been used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

#### 2. Continuing treatment for third-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

#### 3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale,

must be conducted and the result must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - third-line therapy

#### **Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting, **AND**
- Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition, **AND**
- Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of dasatinib is defined as:

(i) Lack of response to second-line dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib for patients initially treated in chronic phase; or
- failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
- (3) Peripheral basophils greater than or equal to 20%; or
- (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib and dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

12887G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3780.40	31.60	Tasigna [NV]

**■ NILOTINIB**
**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - FIRST-LINE THERAPY**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia (CML) in the first line treatment setting. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

**1. Initial First-line treatment**

A patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

**2. Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% on the international scale (Blood 108:28-37,2006) to receive continuing therapy.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

**3. Authority approval requirements**

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with imatinib, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

**4. Definitions of response**

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

**5. Definitions of loss of response**

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - first-line therapy

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**

- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved. Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records.

### nilotinib 150 mg capsule, 120

1309X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2893.12	31.60	Tasigna [NV]

## ■ NILOTINIB

### Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA - SECOND-LINE THERAPY

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia (CML) in the second-line treatment setting.

Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib.

Patients are eligible for PBS-subsidised second-line treatment of CML if they have experienced treatment failure in the first-line treatment setting.

Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib if they have not failed prior PBS-subsidised treatment with either dasatinib or nilotinib in the first-line treatment setting. Patients are eligible for PBS-subsidised treatment with either dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent and may only occur for reasons of intolerance.

Dasatinib is PBS-subsidised for all phases of CML (chronic, accelerated and blast phase) in the second-line treatment setting.

Nilotinib is PBS-subsidised for chronic and accelerated phase CML in the second-line setting. Nilotinib is not approved for patients in blast crisis in any (first, second, third-line) treatment setting.

Imatinib is not approved for second-line treatment of CML.

#### 1. Initial second-line treatment

A patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

#### 2. Continuing treatment for second-line treatment

For continuing applications, patients must demonstrate response to PBS-subsidised treatment as follows:

- within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108:28-37,2006) has been demonstrated may receive authorisation for a further 12 months of treatment; and
- at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

All pathology reports must be documented in the patient's medical records.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

#### 3. Authority approval requirements

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted and the results must be documented in the patient's medical records. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted and the results must be documented in the patient's medical records. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted and the results must be documented in the patient's medical records within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

#### 4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

#### 5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by

at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment - second-line therapy

**Clinical criteria:**

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:

- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to.

50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.

Pathology report(s) confirming a loss of response to imatinib or dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records.

**nilotinib 200 mg capsule, 120**

9171Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3780.40	31.60	Tasigna [NV]

▪ **PONATINIB**

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR

- The condition must have the transcript BCR-ABL, **AND**
  - Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
  - Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.
- Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and
3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or
4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acute lymphoblastic leukaemia  
Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **ponatinib 15 mg tablet, 60**

11454W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5490.78	31.60	Iclusig [TK]

#### **ponatinib 45 mg tablet, 30**

11453T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6174.25	31.60	Iclusig [TK]

### **■ PONATINIB**

#### **Authority required**

Acute lymphoblastic leukaemia  
Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;
3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acute lymphoblastic leukaemia  
Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **ponatinib 15 mg tablet, 60**

10523W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5490.78	31.60	Iclusig [TK]

#### **ponatinib 45 mg tablet, 30**

10524X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6174.25	31.60	Iclusig [TK]

### **■ PONATINIB**

**Note** 1. Continuing treatment.

For first continuing applications patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment.

2. Authority approval requirements.

Response criteria to treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted within 18 months of the commencement of treatment with ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive first continuing treatment with this drug).

Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive subsequent continuing treatments with this drug.

3. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006).

#### 4. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

#### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

- (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or
- (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
- (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available



on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

## **Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals.

The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or
- (ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.

A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **ponatinib 15 mg tablet, 60**

10520Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5490.78	31.60	Iclusig [TK]

**ponatinib 45 mg tablet, 30**

10530F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6174.25	31.60	Iclusig [TK]

**Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors**
**■ AFATINIB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**afatinib 20 mg tablet, 28**

11335N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 30 mg tablet, 28**

11341X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 40 mg tablet, 28**

11359W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 50 mg tablet, 28**

11329G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**■ AFATINIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**7613**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**afatinib 20 mg tablet, 28**

11336P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 30 mg tablet, 28**

11348G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 40 mg tablet, 28**

11347F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**afatinib 50 mg tablet, 28**

11342Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2750.40	31.60	Giotrif [BY]

**■ ERLOTINIB****Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 150 mg tablet, 30**

10014C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	538.63	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 25 mg tablet, 30**

10022L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	126.54	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 100 mg tablet, 30**

10020J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	437.02	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**■ ERLOTINIB****Authority required (STREAMLINED)****4600**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

**erlotinib 150 mg tablet, 30**

10025P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	538.63	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 25 mg tablet, 30**

10028T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	126.54	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 100 mg tablet, 30**

10019H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	437.02	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**■ ERLOTINIB****Authority required (STREAMLINED)****7446**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 150 mg tablet, 30**

11259N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	538.63	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 25 mg tablet, 30**

11263T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	126.54	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**erlotinib 100 mg tablet, 30**

11260P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	437.02	31.60	<sup>a</sup> Erlotinib APOTEX [TX] <sup>a</sup> Erlotinib Sandoz [SZ]	<sup>a</sup> ERLOTINIB ARX [XT]

**■ GEFITINIB**
**Authority required (STREAMLINED)**
**7447**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**gefitinib 250 mg tablet, 30**

11264W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	536.84	31.60	Cipla Gefitinib [LR]

**■ GEFITINIB**
**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**gefitinib 250 mg tablet, 30**

8769M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	536.84	31.60	Cipla Gefitinib [LR]

**■ OSIMERTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**osimertinib 40 mg tablet, 30**

11620N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

**■ OSIMERTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**osimertinib 40 mg tablet, 30**

12233W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

**■ OSIMERTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

**Population criteria:**

- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

**Clinical criteria:**

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug.

**AND**

- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**osimertinib 40 mg tablet, 30**

14162J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

## ■ OSIMERTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

### **Population criteria:**

- Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR
- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

### **Clinical criteria:**

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

### **Treatment criteria:**

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

### **osimertinib 80 mg tablet, 30**

14168Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

## ■ OSIMERTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy

### **Clinical criteria:**

- Patient must not have previously received this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

### **Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

### **Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

### **Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**osimertinib 80 mg tablet, 30**

11622Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

**■ OSIMERTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

**Population criteria:**

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**osimertinib 80 mg tablet, 30**

12232T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7582.10	31.60	Tagrisso [AP]

***B-Raf serine-threonine kinase (BRAF) inhibitors***
**■ DABRAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**



- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**dabrafenib 75 mg capsule, 120**

11823G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7157.83	31.60	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

11820D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	4799.02	31.60	Tafinlar [NV]

**■ DABRAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)****10157**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**dabrafenib 75 mg capsule, 120**

2846T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7157.83	31.60	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

2963Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	4799.02	31.60	Tafinlar [NV]

**■ DABRAFENIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**dabrafenib 75 mg capsule, 120**

10003L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7157.83	31.60	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

2954L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4799.02	31.60	Tafinlar [NV]

**■ DABRAFENIB**

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:

Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. *Cancer*, 53: 2002-2007. [https://doi.org/10.1002/1097-0142\(19840501\)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W](https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W)

**Note** The original publication and validation of the Lansky performance status scale can be found as a free access article here:

Lansky, S.B., List, M.A., Lansky, L.L., Ritter-Sterr, C. and Miller, D.R. (1987), The measurement of performance in childhood cancer patients. *Cancer*, 60: 1651-1656. [https://doi.org/10.1002/1097-0142\(19871001\)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J](https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J)

#### Authority required

Paediatric high grade glioma

Treatment Phase: Initial treatment

#### Clinical criteria:

- The condition must be World Health Organisation (WHO) grade 3 or 4, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%, **AND**
- Patient must have relapsed or progressed following frontline therapy; OR
- Patient must have failed to respond to frontline therapy, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

#### Population criteria:

- Patient must have been aged between 12 months to 18 years at diagnosis.

#### dabrafenib 75 mg capsule, 120

14766E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7157.83	31.60	Tafinlar [NV]

#### dabrafenib 50 mg capsule, 120

14760W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*9489.59	31.60	Tafinlar [NV]

#### dabrafenib 10 mg dispersible tablet, 2 x 210

14752K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*6691.49	31.60	Tafinlar [NV]

### ■ DABRAFENIB

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response in the proposed restrictions is assessed using the Response Assessment for Neuro-Oncology (RANO) 2017 criteria:

Wen PY, Chang SM, Van den Bent MJ, Vogelbaum MA, Macdonald DR, Lee EQ. Response Assessment in Neuro-Oncology Clinical Trials. *J Clin Oncol*. 2017;35(21):2439-2449. doi:10.1200/JCO.2017.72.7511

#### Authority required

Paediatric high grade glioma

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

#### Authority required

Paediatric high grade glioma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025, **AND**
- The condition must have been World Health Organisation (WHO) grade 3 or 4 prior to commencing treatment with this therapy, **AND**
- Patient must have relapsed or progressed following frontline therapy prior to commencing treatment with this therapy; OR
- Patient must have failed to respond to frontline therapy prior to commencing treatment with this therapy, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**

- Patient must have had either a: (i) Karnofsky, (ii) Lansky performance score of at least 50% prior to commencing treatment with this therapy, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Population criteria:**

- Patient must have been aged between 12 months to 18 years prior to commencing treatment with this therapy.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:

Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. *Cancer*, 53: 2002-2007. [https://doi.org/10.1002/1097-0142\(19840501\)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W](https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W)

**Note** The original publication and validation of the Lansky performance status scale can be found as a free access article here:

Lansky, S.B., List, M.A., Lansky, L.L., Ritter-Sterr, C. and Miller, D.R. (1987), The measurement of performance in childhood cancer patients. *Cancer*, 60: 1651-1656. [https://doi.org/10.1002/1097-0142\(19871001\)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J](https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J)

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**dabrafenib 75 mg capsule, 120**

14757Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7157.83	31.60	Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

14755N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*9489.59	31.60	Tafinlar [NV]

**dabrafenib 10 mg dispersible tablet, 2 x 210**

14753L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*6691.49	31.60	Tafinlar [NV]

▪ **DABRAFENIB**

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Paediatric low grade glioma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The condition must have progressed following surgical excision; OR
- The condition must not be amenable to surgery with risk of neurological impairment following progression, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Population criteria:**

- Patient must have been aged between 12 months to 18 years at diagnosis.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:

Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. *Cancer*, 53: 2002-2007. [https://doi.org/10.1002/1097-0142\(19840501\)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W](https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W)

**Note** The original publication and validation of the Lansky performance status scale can be found as a free access article here:

Lansky, S.B., List, M.A., Lansky, L.L., Ritter-Sterr, C. and Miller, D.R. (1987), The measurement of performance in childhood cancer patients. *Cancer*, 60: 1651-1656. [https://doi.org/10.1002/1097-0142\(19871001\)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J](https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J)

**Authority required**

Paediatric low grade glioma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Note** Response in the proposed restrictions is assessed using the Response Assessment for Neuro-Oncology (RANO) 2017 criteria:  
Wen PY, Chang SM, Van den Bent MJ, Vogelbaum MA, Macdonald DR, Lee EQ. Response Assessment in Neuro-Oncology Clinical Trials. J Clin Oncol. 2017;35(21):2439-2449. doi:10.1200/JCO.2017.72.7511

#### Authority required

Paediatric low grade glioma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025, **AND**
- The condition must have been World Health Organisation (WHO) grade 1 or 2 prior to commencing treatment with this therapy, **AND**
- The condition must have progressed following surgical excision prior to commencing treatment with this therapy; OR
- The condition must not have been amenable to surgery with risk of neurological impairment following progression prior to commencing treatment with this therapy, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have had either a: (i) Karnofsky, (ii) Lansky performance score of at least 50% prior to commencing treatment with this therapy, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

#### Population criteria:

- Patient must have been aged between 12 months to 18 years prior to commencing treatment with this therapy.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:  
Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. Cancer, 53: 2002-2007. [https://doi.org/10.1002/1097-0142\(19840501\)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W](https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W)

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**Note** Response in the proposed restrictions is assessed using the Response Assessment for Neuro-Oncology (RANO) 2017 criteria:  
Wen PY, Chang SM, Van den Bent MJ, Vogelbaum MA, Macdonald DR, Lee EQ. Response Assessment in Neuro-Oncology Clinical Trials. J Clin Oncol. 2017;35(21):2439-2449. doi:10.1200/JCO.2017.72.7511

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### dabrafenib 75 mg capsule, 120

14754M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7157.83	31.60	Tafinlar [NV]

#### dabrafenib 50 mg capsule, 120

14778T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*9489.59	31.60	Tafinlar [NV]

#### dabrafenib 10 mg dispersible tablet, 2 x 210

14773M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*6691.49	31.60	Tafinlar [NV]

### ■ ENCORA FENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

12487

Metastatic colorectal cancer

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have BRAF V600 variant positive metastatic colorectal cancer, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have received prior treatment with cetuximab for this condition; OR
- Patient must not have developed disease progression while receiving cetuximab for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have failed to respond to at least one other line of systemic therapy, **AND**
- Patient must have a WHO performance status of 2 or less.

**encorafenib 75 mg capsule, 42**

12814K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*5174.61	31.60	Braftovi [FB]

**■ ENCORAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**12484**

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**encorafenib 75 mg capsule, 42**

12815L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*5174.61	31.60	Braftovi [FB]

**■ ENCORAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**10271**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**encorafenib 50 mg capsule, 28**

11937G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	9	3	..	*7035.15	31.60	Braftovi [FB]

**encorafenib 75 mg capsule, 42**

11938H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*6863.35	31.60	Braftovi [FB]

**■ ENCORAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**encorafenib 50 mg capsule, 28**

11954E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	9	5	..	*7035.15	31.60	Braftovi [FB]

**encorafenib 75 mg capsule, 42**

11949X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*6863.35	31.60	Braftovi [FB]

**■ VEMURAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**10157**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**vemurafenib 240 mg tablet, 56**

11076Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*6691.51	31.60	Zelboraf [RO]

**■ VEMURAFENIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**vemurafenib 240 mg tablet, 56**

11081F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*6691.51	31.60	Zelboraf [RO]

**Anaplastic lymphoma kinase (ALK) inhibitors**
**■ ALECTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**alectinib 150 mg capsule, 4 x 56**

11226W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6483.03	31.60	Alecensa [RO]

**■ BRIGATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**brigatinib 30 mg tablet, 28**

11980M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*6815.71	31.60	Alunbrig [TK]

**brigatinib 180 mg tablet, 28**

11984R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6815.68	31.60	Alunbrig [TK]

**brigatinib 90 mg tablet, 28**

11974F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6815.68	31.60	Alunbrig [TK]

**■ BRIGATINIB**

**Caution** Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack**

11976H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	6815.68	31.60	Alunbrig [TK]

**■ CERITINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**ceritinib 150 mg capsule, 3 x 50**

11056X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Zykadia [NV]

**■ CRIZOTINIB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

- evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### crizotinib 200 mg capsule, 60

10323H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

### crizotinib 250 mg capsule, 60

10322G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

## ■ CRIZOTINIB

**Note** Special Pricing Arrangements apply.

#### Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

#### Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

#### Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### crizotinib 200 mg capsule, 60

11589Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

**crizotinib 250 mg capsule, 60**

11594F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

**■ LORLATINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**lorlatinib 25 mg tablet, 90**

12096P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6765.19	31.60	Lorviqua [PF]

**lorlatinib 100 mg tablet, 30**

12091J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6765.19	31.60	Lorviqua [PF]

**Mitogen-activated protein kinase (MEK) inhibitors**
**■ BINIMETINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10328**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition.

**binimetinib 15 mg tablet, 84**

11948W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*7215.97	31.60	Mektovi [FB]

**■ BINIMETINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**10306**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition, **AND**

- Patient must have stable or responding disease.

#### binimetinib 15 mg tablet, 84

11961M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*7215.97	31.60	Mektovi [FB]

#### ■ COBIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

**10033**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

##### **Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.

#### cobimetinib 20 mg tablet, 63

11074W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7035.11	31.60	Cotellic [RO]

#### ■ COBIMETINIB

**Note** A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

**6803**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

##### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

#### cobimetinib 20 mg tablet, 63

11075X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7035.11	31.60	Cotellic [RO]

#### ■ SELUMETINIB

**Note** The Karnofsky Performance Score is available at:

<https://oncologypro.esmo.org/oncology-in-practice/practice-tools/performance-scales>  
[www.mdcalc.com/calc/3168/karnofsky-performance-status-scale](http://www.mdcalc.com/calc/3168/karnofsky-performance-status-scale)

**Note** The Lansky Performance Score is available at:

[www.mdcalc.com/calc/3176/lansky-play-performance-scale-pediatric-functional-status](http://www.mdcalc.com/calc/3176/lansky-play-performance-scale-pediatric-functional-status)

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Neurofibromatosis type 1

Treatment Phase: Initial treatment

##### **Clinical criteria:**

- Patient must have plexiform neurofibroma(s) (PN) that is causing/likely to cause at least one of: (i) significant symptoms/morbidity, (ii) disability, (iii) disfigurement, (iv) impairment of normal body function, **AND**
- Patient must have PN for which complete resection cannot be performed, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky Performance Score of at least 70%.

##### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

##### **Population criteria:**

- Patient must be aged between 2 to 18 years, **AND**
- Patient must be able to swallow the whole capsule form of this drug.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:

1. head and neck PN that can compromise the airway or great vessels;
2. paraspinal PN that can cause myelopathy;
3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;
4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);
5. PN of the extremity that can cause limb hypertrophy or loss of function; and
6. painful PN.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Neurofibromatosis type 1

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be tolerating treatment, **AND**
- Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment with this drug.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, adequate response is defined as:

1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;
2. relevant imaging has not shown an increase in tumour size of 20% or more.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Neurofibromatosis type 1

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 August 2024; OR
- Patient must have previously received treatment with another mitogen-activated protein kinase (MEK) inhibitor for this condition prior to 1 August 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply of a MEK inhibitor (including selumetinib) was commenced, the patient: (i) had PN that caused/was likely to cause at least one of: (a) significant symptoms/morbidity, (b) disability, (c) disfigurement, (d) impairment of normal body function; (ii) had PN for which complete PN resection could not be performed either: (a) safely, (b) without causing unacceptable morbidity; (iii) had either a: (a) Karnofsky, (b) Lansky Performance Score of at least 70%; (iv) was aged between 2 to 18 years; (v) was able to swallow the whole capsule form if received non-PBS supply with selumetinib, **AND**
- Patient must be tolerating treatment, **AND**
- Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:

1. head and neck PN that can compromise the airway or great vessels;
2. paraspinal PN that can cause myelopathy;
3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;
4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);
5. PN of the extremity that can cause limb hypertrophy or loss of function; and
6. painful PN.

For the purpose of administering this restriction, adequate response is defined as:

1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;
2. relevant imaging has not shown an increase in tumour size of 20% or more.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### selumetinib 10 mg capsule, 60

14236G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7112.60	31.60	Koselugo [XI]

### selumetinib 25 mg capsule, 60

14287Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	17537.60	31.60	Koselugo [XI]

## ■ TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

#### **10051**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.

### trametinib 500 microgram tablet, 30

10403M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*5671.62	31.60	Mekinist [NV]

### trametinib 2 mg tablet, 30

10382K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7526.00	31.60	Mekinist [NV]

## ■ TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**trametinib 500 microgram tablet, 30**

11821E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*5671.62	31.60	Mekinist [NV]

**trametinib 2 mg tablet, 30**

11819C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7526.00	31.60	Mekinist [NV]

▪ **TRAMETINIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6752**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**trametinib 500 microgram tablet, 30**

10385N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*5671.62	31.60	Mekinist [NV]

**trametinib 2 mg tablet, 30**

10405P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7526.00	31.60	Mekinist [NV]

▪ **TRAMETINIB**

**Note** Trametinib is available as tablets and oral solution. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Paediatric high grade glioma

**Clinical criteria:**

- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**trametinib 500 microgram tablet, 30**

14780X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*7526.03	31.60	Mekinist [NV]

**trametinib 2 mg tablet, 30**

14774N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7526.00	31.60	Mekinist [NV]

**trametinib 50 microgram/mL powder for oral liquid, 90 mL**

14742X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	13	3	..	*7660.99	31.60	Mekinist [NV]

■ **TRAMETINIB**

**Note** Trametinib is available as tablets and oral solution. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Paediatric low grade glioma

**Clinical criteria:**

- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**trametinib 500 microgram tablet, 30**

14779W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*7526.03	31.60	Mekinist [NV]

**trametinib 2 mg tablet, 30**

14767F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7526.00	31.60	Mekinist [NV]

**trametinib 50 microgram/mL powder for oral liquid, 90 mL**

14761X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	13	3	..	*7660.99	31.60	Mekinist [NV]

*Cyclin-dependent kinase (CDK) inhibitors*

■ **ABEMACICLIB**

**Note** The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details: Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. *Histopathology*. 1991 Nov;19(5):403-10.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Early breast cancer

**Clinical criteria:**

- The treatment must be adjuvant to surgical resection, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**abemaciclib 50 mg tablet, 56**

14116Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]

**abemaciclib 100 mg tablet, 56**

14105J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]

**abemaciclib 150 mg tablet, 56**

14134X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]

**■ ABEMACICLIB**

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**abemaciclib 50 mg tablet, 56**

11876C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]

**abemaciclib 100 mg tablet, 56**

11871T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]



### abemaciclib 150 mg tablet, 56

11868P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4046.06	31.60	Verzenio [LY]

### ■ PALBOCICLIB

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

#### **Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

#### Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

#### **Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

### palbociclib 100 mg tablet, 21

12819Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3657.72	31.60	Ibrance [PF]

### palbociclib 125 mg tablet, 21

12822W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3657.72	31.60	Ibrance [PF]

### palbociclib 75 mg tablet, 21

12818P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3657.72	31.60	Ibrance [PF]

### ■ RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

#### Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

#### Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

#### Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

#### ribociclib 200 mg tablet, 21

11385F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1847.51	31.60	Kisqali [NV]

#### ■ RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.
- PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Population criteria:**

- Patient must not be premenopausal.
- PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 63**

11386G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5254.62	31.60	Kisqali [NV]

▪ **RIBOCICLIB**

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**

- Patient must not be premenopausal.
- PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority required**

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 42**

11397W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3557.28	31.60	Kisqali [NV]

*Mammalian target of rapamycin (mTOR) kinase inhibitors*

▪ **EVEROLIMUS**

Authority required (STREAMLINED)

**7431**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**everolimus 2.5 mg tablet, 30**

11258M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	458.19	31.60	Afinitor [NV]

**everolimus 10 mg tablet, 30**

11267B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1738.38	31.60	Afinitor [NV]

**everolimus 5 mg tablet, 30**

11254H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.84	31.60	Afinitor [NV]

▪ **EVEROLIMUS**

Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**everolimus 2.5 mg tablet, 30**

2818H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	458.19	31.60	Afinitor [NV]

▪ **EVEROLIMUS**

**Note** No increase in the maximum number of repeats may be authorised.

Authority required

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**Population criteria:**

- Patient must be at least 2 years of age.

**everolimus 2 mg dispersible tablet, 30**

11591C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	368.15	31.60	Afinitor [NV]

**everolimus 3 mg dispersible tablet, 30**

11599L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	547.99	31.60	Afinitor [NV]

**everolimus 5 mg dispersible tablet, 30**

11592D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.63	31.60	Afinitor [NV]

**■ EVEROLIMUS**

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**8262**

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**everolimus 2 mg dispersible tablet, 30**

11607X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	368.15	31.60	Afinitor [NV]

**everolimus 3 mg dispersible tablet, 30**

11608Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	547.99	31.60	Afinitor [NV]

**everolimus 5 mg dispersible tablet, 30**

11598K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.63	31.60	Afinitor [NV]

**■ EVEROLIMUS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
  - Patient must not have disease progression, **AND**
  - The treatment must be as monotherapy.
- Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 10 mg tablet, 30**

10135K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1738.38	31.60	Afinitor [NV]

**everolimus 5 mg tablet, 30**

10131F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.84	31.60	Afinitor [NV]

**■ EVEROLIMUS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR

- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

#### everolimus 10 mg tablet, 30

11377T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1738.38	31.60	Afinitor [NV]

#### everolimus 5 mg tablet, 30

11362B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	901.84	31.60	Afinitor [NV]

### ■ EVEROLIMUS

#### Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

#### Authority required

Metastatic (Stage IV) breast cancer

#### **Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

#### **Population criteria:**

- Patient must not be pre-menopausal.

**Note** Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

#### everolimus 10 mg tablet, 30

2985D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1738.38	31.60	Afinitor [NV]

#### everolimus 5 mg tablet, 30

2819J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.84	31.60	Afinitor [NV]

### ■ EVEROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

#### Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

#### everolimus 10 mg tablet, 30

10132G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1738.38	31.60	Afinitor [NV]

**everolimus 5 mg tablet, 30**

10133H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	901.84	31.60	Afinitor [NV]

▪ **EVEROLIMUS**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**7432**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 10 mg tablet, 30**

11262R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1738.38	31.60	Afinitor [NV]

**everolimus 5 mg tablet, 30**

11257L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	901.84	31.60	Afinitor [NV]

*Human epidermal growth factor receptor 2 (HER2) tyrosine kinase inhibitors*

▪ **LAPATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**9360**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

**lapatinib 250 mg tablet, 70**

11251E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*2210.49	31.60	Tykerb [NV]

▪ **LAPATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
- Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR
- Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and

(ii) date of last treatment with a taxane and total number of cycles; or

(iii) dates of treatment with trastuzumab and pertuzumab; or

(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or

(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

All reports must be documented in the patient's medical records.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

If the application is submitted through HPOS upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### lapatinib 250 mg tablet, 70

9148L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*2210.49	31.60	Tykerb [NV]

#### Janus-associated kinase (JAK) inhibitors

#### ■ MOMELLOTINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**16367**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

#### Authority required (STREAMLINED)

**16373**

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**



- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**momelotinib 100 mg tablet, 30**

14743Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5800.38	31.60	Omijara [GK]

**momelotinib 150 mg tablet, 30**

14744B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5800.38	31.60	Omijara [GK]

**momelotinib 200 mg tablet, 30**

14770J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5800.38	31.60	Omijara [GK]

**■ MOMELOTINIB**

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; OR
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**momelotinib 100 mg tablet, 30**

14769H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5800.38	31.60	Omijara [GK]

**momelotinib 150 mg tablet, 30**

14762Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5800.38	31.60	Omijara [GK]

**momelotinib 200 mg tablet, 30**

14763B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5800.38	31.60	Omijara [GK]

**■ RUXOLITINIB**

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16367**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Authority required (STREAMLINED)**

**16373**

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**ruxolitinib 10 mg tablet, 56**

10927D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4912.61	31.60	Jakavi [NV]

**ruxolitinib 15 mg tablet, 56**

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

**ruxolitinib 20 mg tablet, 56**

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

■ **RUXOLITINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13906**

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**

- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

The severity of cGVHD is defined by the **National Institutes of Health (NIH)** criteria (Jagasia et al., 2015):

(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1

(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health (NIH)** criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

#### **Authority required (STREAMLINED)**

**13867**

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

#### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as defined by the **National Institutes of Health (NIH)** criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

#### **ruxolitinib 10 mg tablet, 56**

13235N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4912.60	31.60	Jakavi [NV]

#### **ruxolitinib 5 mg tablet, 56**

13241X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2510.53	31.60	Jakavi [NV]

### **■ RUXOLITINIB**

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority required**

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; OR
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**ruxolitinib 10 mg tablet, 56**

10613J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

10614P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*4912.61	31.60	Jakavi [NV]

**ruxolitinib 15 mg tablet, 56**

10619X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

**ruxolitinib 20 mg tablet, 56**

10618W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4912.60	31.60	Jakavi [NV]

**Vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors****■ AXITINIB****Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required (STREAMLINED)****7433**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
  - Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**axitinib 1 mg tablet, 28**

10539Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1070.79	31.60	Inlyta [PF]

**axitinib 5 mg tablet, 28**

10556N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4950.61	31.60	Inlyta [PF]

**■ AXITINIB****Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

#### Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

#### axitinib 1 mg tablet, 28

10572K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1070.79	31.60	Inlyta [PF]

#### axitinib 5 mg tablet, 28

10540R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4950.61	31.60	Inlyta [PF]

#### Bruton's tyrosine kinase (BTK) inhibitors

#### ■ ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

#### Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

#### Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

#### acalabrutinib 100 mg tablet, 56

13318Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7414.57	31.60	CALQUENCE [AP]

#### ■ ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - as monotherapy

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

**acalabrutinib 100 mg tablet, 56**

13792X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7414.57	31.60	CALQUENCE [AP]

**■ ACALABRUTINIB**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - in combination with obinutuzumab

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

**acalabrutinib 100 mg tablet, 56**

13810W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	7414.57	31.60	CALQUENCE [AP]

**■ ACALABRUTINIB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR

- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

#### Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

#### Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

#### acalabrutinib 100 mg tablet, 56

13325H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7414.57	31.60	CALQUENCE [AP]

#### ■ IBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:  
Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

#### Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

#### Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

#### ibrutinib 140 mg capsule, 90

11213E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

#### ibrutinib 280 mg tablet, 30

14074R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.97	31.60	Imbruvica [JC]

#### ibrutinib 420 mg tablet, 30

14085H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

#### ■ IBRUTINIB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment (treatment cycles 10 to 15 inclusive) of first-line therapy

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**

- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 15 cycles of treatment with this drug for this condition, whichever comes first.

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

14596F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7954.15	31.60	Imbruvica [JC]

**ibrutinib 280 mg tablet, 30**

14612C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	5356.97	31.60	Imbruvica [JC]

**ibrutinib 420 mg tablet, 30**

14621M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7954.15	31.60	Imbruvica [JC]

**■ IBRUTINIB**

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 4 to 9 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

14604P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

**ibrutinib 280 mg tablet, 30**

14620L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.97	31.60	Imbruvica [JC]

**ibrutinib 420 mg tablet, 30**

14603N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

**■ IBRUTINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.



**Authority required**

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**ibrutinib 280 mg tablet, 30**

14079B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.97	31.60	Imbruvica [JC]

**ibrutinib 420 mg tablet, 30**

14075T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

**ibrutinib 560 mg tablet, 30**

14086J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10551.33	31.60	Imbruvica [JC]

**ibrutinib 140 mg capsule, 120**

11419B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10551.33	31.60	Imbruvica [JC]

**■ IBRUTINIB**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy (treatment cycles 1 to 3 inclusive)

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses).

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

14597G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	7954.15	31.60	Imbruvica [JC]

**ibrutinib 280 mg tablet, 30**

14580J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5356.97	31.60	Imbruvica [JC]

**ibrutinib 420 mg tablet, 30**

14598H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	7954.15	31.60	Imbruvica [JC]

**■ IBRUTINIB**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### **Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply of first-line therapy

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2024, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The condition must have been untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line treatment of CLL/SLL at the time of receiving non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the next relevant treatment phase.

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

#### **ibrutinib 140 mg capsule, 90**

14613D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

#### **ibrutinib 280 mg tablet, 30**

14579H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.97	31.60	Imbruvica [JC]

#### **ibrutinib 420 mg tablet, 30**

14619K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7954.15	31.60	Imbruvica [JC]

### **■ ZANUBRUTINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

#### **Authority required**

Waldenstrom macroglobulinaemia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; OR
- Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naïve) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.

#### **Authority required**

Waldenstrom macroglobulinaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**zanubrutinib 80 mg capsule, 120**

13041J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7932.56	31.60	Brukina [IE]

▪ **ZANUBRUTINIB**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

**zanubrutinib 80 mg capsule, 120**

13616P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7932.56	31.60	Brukina [IE]

▪ **ZANUBRUTINIB**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.

**zanubrutinib 80 mg capsule, 120**

13628G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7932.56	31.60	Brukina [IE]

**■ ZANUBRUTINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Authority required**

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**zanubrutinib 80 mg capsule, 120**

12891L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7932.56	31.60	Brukina [IE]

***Phosphatidylinositol-3-kinase (Pi3K) inhibitors***
**■ IDELALISIB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**12480**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**idelalisib 100 mg tablet, 60**

12813J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

**idelalisib 150 mg tablet, 60**

12812H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

**■ IDELALISIB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records.

#### idelalisib 100 mg tablet, 60

11171Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

#### idelalisib 150 mg tablet, 60

11165P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

### ■ IDELALISIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

#### Clinical criteria:

- The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR
- The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; OR
- Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

#### idelalisib 100 mg tablet, 60

11170X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

#### idelalisib 150 mg tablet, 60

11162L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5119.46	31.60	Zydelig [GI]

#### Other protein kinase inhibitors

### ■ CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

- (i) a time of diagnosis to systemic therapy of less than 1 year
- (ii) a Karnofsky Performance Status of less than 80%
- (iii) a haemoglobin less than the lower limit of normal
- (iv) a corrected calcium level greater than the upper limit of normal
- (v) a neutrophil count greater than the upper limit of normal
- (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

#### **Authority required (STREAMLINED)**

**15774**

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Treatment criteria:**

- Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.

#### **cabozantinib 20 mg tablet, 30**

11371L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

#### **cabozantinib 40 mg tablet, 30**

11369J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

#### **cabozantinib 60 mg tablet, 30**

11360X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

### **■ CABOZANTINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** Vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor's (TKI) include: lenvatinib.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**15454**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be refractory to radioactive iodine; OR
- Patient must be deemed ineligible for treatment with radioactive iodine, **AND**
- Patient must have progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) for this indication; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy, **AND**
- Patient must have a WHO performance status of no higher than 2, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have thyroid stimulating hormone adequately suppressed.

Radioactive iodine refractory is defined as:

- (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- (iii) progression within 12 months of a single RAI treatment; or
- (iv) progression after two RAI treatments administered within 12 months of each other.

#### **cabozantinib 20 mg tablet, 30**

14265T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

#### **cabozantinib 40 mg tablet, 30**

14246T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

#### **cabozantinib 60 mg tablet, 30**

14224P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

### ■ CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**15775**

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

#### **Authority required (STREAMLINED)**

**15757**

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2024, **AND**
- Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Note** A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

- (i) a time of diagnosis to systemic therapy of less than 1 year
- (ii) a Karnofsky Performance Status of less than 80%
- (iii) a haemoglobin less than the lower limit of normal
- (iv) a corrected calcium level greater than the upper limit of normal
- (v) a neutrophil count greater than the upper limit of normal
- (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Maintenance treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**cabozantinib 20 mg tablet, 30**

11374P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

**cabozantinib 40 mg tablet, 30**

11368H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

**cabozantinib 60 mg tablet, 30**

11367G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

**■ CABOZANTINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**15479**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine; OR
- Patient must be deemed ineligible for treatment with radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Authority required (STREAMLINED)**
**15518**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024, **AND**
- The condition must be refractory to radioactive iodine; OR
- Patient must be deemed ineligible for treatment with radioactive iodine, **AND**
- Patient must have had progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) prior to receiving this drug for this indication; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy prior to receiving this drug for this indication, **AND**
- Patient must have had a WHO performance status of no greater than 2 prior to receiving this drug for this indication, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have thyroid stimulating hormone adequately suppressed.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

**Note** Vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor's (TKI) include: lenvatinib.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**cabozantinib 20 mg tablet, 30**

14297L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]



**cabozantinib 40 mg tablet, 30**

14254F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

**cabozantinib 60 mg tablet, 30**

14237H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

▪ **ENTRECTINIB**

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

- (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**entrectinib 200 mg capsule, 90**

12092K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7290.90	31.60	Rozlytrek [RO]

▪ **GILTERITINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not be for maintenance therapy post-transplant.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- (a) Leukaemic cells in the CSF; or
- (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or
- (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or
- (d) Extramedullary leukaemia.

**gilteritinib 40 mg tablet, 84**

13094E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	25145.60	31.60	Xospata [LL]

**■ GILTERITINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation, **AND**
- The treatment must not be for maintenance therapy post-transplant.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

**gilteritinib 40 mg tablet, 84**

13093D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	25145.60	31.60	Xospata [LL]

**■ LAROTRECTINIB**

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of any type) with confirmed NTRK gene fusion where treatment with this drug is/was initiated in a child; OR
- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of certain specified types) with confirmed NTRK gene fusion which either includes: (i) mammary analogue secretory carcinoma of the salivary gland, (ii) secretory breast carcinoma.

**Clinical criteria:**

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

13289K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3462.60	31.60	Vitrakvi [BN]

**larotrectinib 100 mg capsule, 56**

13043L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10062.60	31.60	Vitrakvi [BN]

**larotrectinib 25 mg capsule, 56**

13027P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2637.60	31.60	Vitrakvi [BN]

▪ **LAROTRECTINIB**

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion  
Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be non-small cell lung cancer confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be soft tissue sarcoma confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be confirmed through a pathology report from an Approved Pathology Authority (of any date) as either: (i) glioma, (ii) glioneuronal tumour, (iii) glioblastoma, **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be locally advanced where surgical resection is likely to result in severe morbidity, **AND**
- Patient must have received prior systemic treatment for this disease; OR
- Patient must have a condition that predisposes them to an unacceptable risk of intolerance to other systemic therapies, **AND**
- The treatment must be the sole PBS-subsidised anti-cancer therapy for this condition, **AND**
- Patient must not receive more than 3 months of treatment under this restriction.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (non-small cell lung cancer, soft tissue sarcoma or either glioma/ glioneuronal tumour/ glioblastoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

(c) details of prior systemic treatment for this disease or details of the condition that predisposes the patient to an unacceptable risk of intolerance to other systemic therapies.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

14230Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3462.60	31.60	Vitrakvi [BN]

#### larotrectinib 100 mg capsule, 56

14300P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	10062.60	31.60	Vitrakvi [BN]

#### larotrectinib 25 mg capsule, 56

14257J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2637.60	31.60	Vitrakvi [BN]

### ■ LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be either: (i) non-small cell lung cancer, (ii) soft tissue sarcoma, (iii) glioma, (iv), glioneuronal tumour, (v) glioblastoma, **AND**
- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

#### larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

14256H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3462.60	31.60	Vitrakvi [BN]

#### larotrectinib 100 mg capsule, 56

14282Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10062.60	31.60	Vitrakvi [BN]

#### larotrectinib 25 mg capsule, 56

14258K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2637.60	31.60	Vitrakvi [BN]

### ■ LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

#### **Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

#### **Population criteria:**

- Patient must be/have been under 18 years of age (i.e. prior to their 18<sup>th</sup> birthday) at treatment initiation with this drug. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### **Authority required**

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); OR
- The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date), **AND**
- The condition must be metastatic disease; OR
- The condition must be both: (i) locally advanced, (ii) unresectable; OR
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

#### **Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

13281B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3462.60	31.60	Vitrakvi [BN]

**larotrectinib 100 mg capsule, 56**

13031W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	10062.60	31.60	Vitrakvi [BN]

**larotrectinib 25 mg capsule, 56**

13029R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2637.60	31.60	Vitrakvi [BN]

**■ LENVATINIB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**11168**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

**Authority required (STREAMLINED)**

**8584**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**lenvatinib 4 mg capsule, 30**

11638M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*6162.60	31.60	Lenvima [EI]

**■ LENVATINIB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**15510**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
  - Patient must have symptomatic progressive disease prior to treatment; OR
  - Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
  - Patient must have thyroid stimulating hormone adequately suppressed, **AND**
  - Patient must be one in whom surgery is inappropriate, **AND**
  - Patient must not be a candidate for radiotherapy with curative intent, **AND**
  - Patient must have a WHO performance status of 2 or less.
- Radioactive iodine refractory is defined as:
- (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
  - (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or
  - (iii) progression within 12 months of a single RAI treatment; or
  - (iv) progression after two RAI treatments administered within 12 months of each other.

**Authority required (STREAMLINED)**

**6578**

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**lenvatinib 10 mg capsule, 30**

10965D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4162.61	31.60	Lenvima [EI]

**lenvatinib 4 mg capsule, 30**

10952K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2126.51	31.60	Lenvima [EI]

▪ **LENVATINIB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13921**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

- (i) a time of diagnosis to systemic therapy of less than 1 year
- (ii) a Karnofsky Performance Status of less than 80%
- (iii) a haemoglobin less than the lower limit of normal
- (iv) a corrected calcium level greater than the upper limit of normal
- (v) a neutrophil count greater than the upper limit of normal
- (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

**Authority required (STREAMLINED)**

**13972**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR

- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.
- In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

**lenvatinib 4 mg capsule, 30**

13252L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4144.57	31.60	Lenvima [EI]

**■ LENVATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****14042**

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior treatment with platinum-based chemotherapy, **AND**
- The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Authority required (STREAMLINED)****14041**

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

**lenvatinib 10 mg capsule, 30**

13283D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4162.61	31.60	Lenvima [EI]

**lenvatinib 4 mg capsule, 30**

13290L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4144.57	31.60	Lenvima [EI]

**■ LENVATINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****13921**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR



- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

**Note A** prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

- (i) a time of diagnosis to systemic therapy of less than 1 year
- (ii) a Karnofsky Performance Status of less than 80%
- (iii) a haemoglobin less than the lower limit of normal
- (iv) a corrected calcium level greater than the upper limit of normal
- (v) a neutrophil count greater than the upper limit of normal
- (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

#### **Authority required (STREAMLINED)**

##### **13972**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

#### **Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

#### **lenvatinib 10 mg capsule, 30**

13253M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4162.61	31.60	Lenvima [EI]

#### **■ NINTEDANIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

#### **Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii)

continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **nintedanib 100 mg capsule, 60**

11100F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1680.06	31.60	Ofev [BY]

#### **nintedanib 150 mg capsule, 60**

11106M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3238.32	31.60	Ofev [BY]

## ■ NINTEDANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Progressive fibrosing Interstitial lung disease

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication, **AND**
- The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5), **AND**
- Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of: (i) age, (ii) gender, (iii) height, **AND**
- The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted, **AND**
- The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is), **AND**
- The condition must not be due to reversible causes (e.g. drug toxicity).

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- a completed authority prescription form; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

**Note** Interstitial lung disease includes, but is not limited to:

- connective tissue associated interstitial lung disease;
- chronic fibrosing hypersensitivity pneumonitis;
- idiopathic non-specific interstitial pneumonia;
- pulmonary sarcoidosis.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Progressive fibrosing Interstitial lung disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nintedanib 100 mg capsule, 60**

12967L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1680.06	31.60	Ofev [BY]

**nintedanib 150 mg capsule, 60**

12953R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3238.32	31.60	Ofev [BY]

■ **PAZOPANIB**

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

**11939**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
  - Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
  - Patient must require dose adjustment, **AND**
  - The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
- A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
- PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 30**

2232L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1137.85	31.60	Votrient [NV]

**pazopanib 400 mg tablet, 30**

2201W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2205.54	31.60	Votrient [NV]

■ **PAZOPANIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9247**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less, **AND**
  - Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
  - Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Patient must not have any of the following conditions:

adipocytic soft tissue sarcoma;  
gastrointestinal stromal tumour (GIST);  
rhabdomyosarcoma other than alveolar or pleomorphic;  
chondrosarcoma;  
osteosarcoma;  
Ewings tumour/primitive neuroectodermal tumour;  
dermofibromatosis sarcoma protuberans;  
inflammatory myofibroblastic sarcoma;  
malignant mesothelioma;  
mixed mesodermal tumour of the uterus.

### pazopanib 200 mg tablet, 90

10042M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3227.01	31.60	Votrient [NV]

### pazopanib 400 mg tablet, 60

10041L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4248.48	31.60	Votrient [NV]

## ■ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**7458**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

#### **Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### pazopanib 200 mg tablet, 90

10047T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3227.01	31.60	Votrient [NV]

### pazopanib 400 mg tablet, 60

10043N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4248.48	31.60	Votrient [NV]

## ■ PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**7459**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

#### **Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**pazopanib 200 mg tablet, 30**

10054E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1137.85	31.60	Votrient [NV]

**pazopanib 400 mg tablet, 30**

10052C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2205.54	31.60	Votrient [NV]

**■ PAZOPANIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)****11937**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
  - Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
  - The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
- A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
- PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 90**

11252F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3227.01	31.60	Votrient [NV]

**pazopanib 400 mg tablet, 60**

11261Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4248.48	31.60	Votrient [NV]

**■ PAZOPANIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required (STREAMLINED)****11974**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
  - Patient must have a WHO performance status of 2 or less, **AND**
  - The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
- PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**pazopanib 200 mg tablet, 90**

2029T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3227.01	31.60	Votrient [NV]

**pazopanib 400 mg tablet, 60**

2030W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4248.48	31.60	Votrient [NV]

## ▪ RIPRETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Special Pricing Arrangements apply.

### **Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; OR
- The condition must have progressed despite each of: (i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication, **AND**
- Patient must have a WHO performance status of 2 or less.

### **Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug for the first time - retreatment/continuing treatment beyond the available repeat prescription is not permitted under this listing; see 'Continuing treatment' Treatment Phase listing to continue PBS-subsidised treatment in a patient without disease progression.

**Note** Currently PBS-listed drugs with the indication of: 'metastatic or unresectable malignant gastrointestinal stromal tumour' are: imatinib and sunitinib

### **Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- The condition must not be resectable, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

## ripretinib 50 mg tablet, 90

12764T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	16304.54	31.60	Qinlock [ZB]

## ▪ SELPERCATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required (STREAMLINED)**

**16270**

Locally advanced or metastatic non-small cell lung cancer

### **Clinical criteria:**

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; OR
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

## selpercatinib 40 mg capsule, 56

14693H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2137.60	31.60	Retevmo [LY]

## ▪ SELPERCATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required (STREAMLINED)**

**16282**

Locally advanced or metastatic non-small cell lung cancer

**Clinical criteria:**

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; OR
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Medical practitioners may prescribe selpercatinib 80 mg with a quantity of up to 56 units where the dose does not exceed 120 mg twice daily (i.e., in combination with selpercatinib 40 mg). Selpercatinib 80 mg with a quantity of 112 units must be prescribed only where the dose is 160 mg twice daily to provide 28 days of treatment per dispensing. Prescribers should refer to the TGA PI for dosing and dose adjustments regimens.

**selpercatinib 80 mg capsule, 56**

14703W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*8062.61	31.60	Retevmo [LY]

**■ SORAFENIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sorafenib 200 mg tablet, 60**

10226F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4150.01	31.60	Nexavar [BN]

**■ SORAFENIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****7487**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.



**sorafenib 200 mg tablet, 60**

10242C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4150.01	31.60	Nexavar [BN]

▪ **SORAFENIB**

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**11160**

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy.

**Authority required (STREAMLINED)**

**8617**

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**sorafenib 200 mg tablet, 60**

9380Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4150.01	31.60	Nexavar [BN]

▪ **SUNITINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**sunitinib 37.5 mg capsule, 28**

10464R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 12.5 mg capsule, 28**

10004M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

**sunitinib 25 mg capsule, 28**

2959R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 50 mg capsule, 28**

2837H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT]	<sup>a</sup> Sunitinib Sandoz [SZ]

<sup>a</sup> Sutent [PF]▪ **SUNITINIB****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****7471**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sunitinib 37.5 mg capsule, 28**

10473F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 12.5 mg capsule, 28**

10009T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

**sunitinib 25 mg capsule, 28**

2842N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 50 mg capsule, 28**

10010W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

▪ **SUNITINIB****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)****11875**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**sunitinib 37.5 mg capsule, 28**

10459L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 12.5 mg capsule, 28**

9420T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

**sunitinib 25 mg capsule, 28**

9421W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

# sunitinib 50 mg capsule, 28

9422X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

## ■ SUNITINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour  
Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

# sunitinib 37.5 mg capsule, 28

10503T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

# sunitinib 12.5 mg capsule, 28

9488J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

# sunitinib 25 mg capsule, 28

9489K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

# sunitinib 50 mg capsule, 28

9490L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

## ■ SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

### **Authority required (STREAMLINED)**

**11878**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**

- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition. PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**sunitinib 37.5 mg capsule, 28**

10504W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 12.5 mg capsule, 28**

9417P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

**sunitinib 25 mg capsule, 28**

9418Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 50 mg capsule, 28**

9419R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**■ SUNITINIB**

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****13153**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**sunitinib 37.5 mg capsule, 28**

11256K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1691.82	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 12.5 mg capsule, 28**

11266Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	588.24	31.60	<sup>a</sup> Sunitinib Sandoz [SZ]	<sup>a</sup> Sutent [PF]

**sunitinib 25 mg capsule, 28**

11253G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1150.57	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**sunitinib 50 mg capsule, 28**

11250D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2255.28	31.60	<sup>a</sup> ARX-Sunitinib [XT] <sup>a</sup> Sutent [PF]	<sup>a</sup> Sunitinib Sandoz [SZ]

**■ TEPOTINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****13434**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of MET exon 14 skipping alterations in tumour material.

**Authority required (STREAMLINED)**
**13441**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**tepotinib 225 mg tablet, 60**

13171F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9104.80	31.60	Tepmetko [SG]

**MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES**
**CD38 (Clusters of Differentiation 38) inhibitors**
**■ DARATUMUMAB**

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

**Treatment criteria:**

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

Progressive disease is defined as at least 1 of the following:

- at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- an increase in the size or number of lytic bone lesions (not including compression fractures); or
- at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- the level of serum monoclonal protein; or
- Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- the serum level of free kappa and lambda light chains; or
- bone marrow aspirate or trephine; or
- if present, the size and location of lytic bone lesions (not including compression fractures); or
- if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

#### daratumumab 1.8 g/15 mL injection, 15 mL vial

12683M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	7172.88	31.60	Darzalex SC [JC]

#### ■ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

##### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have developed disease progression while receiving treatment with this drug for this condition.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
  - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
  - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
  - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
  - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
  - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
  - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

#### daratumumab 1.8 g/15 mL injection, 15 mL vial

12725R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7172.88	31.60	Darzalex SC [JC]

#### ■ DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

##### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - The treatment must be in combination with bortezomib and dexamethasone, **AND**
  - Patient must not have developed disease progression while receiving treatment with this drug for this condition.
- Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

#### daratumumab 1.8 g/15 mL injection, 15 mL vial

12755H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7172.88	31.60	Darzalex SC [JC]

#### ■ DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

##### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

##### Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

#### daratumumab 1.8 g/15 mL injection, 15 mL vial

13199Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7172.88	31.60	Darzalex SC [JC]

#### ■ DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

PBS Authorities

GPO Box 9826

[Your capital city]

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Initial treatment from week 0 to week 24

##### Clinical criteria:

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

##### Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**

- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### daratumumab 1.8 g/15 mL injection, 15 mL vial

13202W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	15	..	7172.88	31.60	Darzalex SC [JC]

#### HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors

#### ■ TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

##### Authority required (STREAMLINED)

**10212**

Early HER2 positive breast cancer

Treatment Phase: 3 weekly treatment regimen

##### **Clinical criteria:**

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1609.04	31.60	Herceptin SC [RO]

#### ■ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

##### Authority required (STREAMLINED)

**9353**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

##### **Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

10798H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1609.04	31.60	Herceptin SC [RO]

#### ■ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

##### Authority required (STREAMLINED)

**9462**

Metastatic (Stage IV) HER2 positive breast cancer



Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10803N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1609.04	31.60	Herceptin SC [RO]

**PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors**

▪ **ATEZOLIZUMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10216**

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14267X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	6909.97	31.60	Tecentriq SC [RO]

▪ **ATEZOLIZUMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10297**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have stable or responding disease.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14288B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	6909.97	31.60	Tecentriq SC [RO]

▪ **ATEZOLIZUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10521**

Extensive-stage small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14225Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	6909.97	31.60	Tecentriq SC [RO]

▪ **ATEZOLIZUMAB**

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**13443**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 3 weekly treatment regimen

**Clinical criteria:**

- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; OR
- The condition must have progressed after treatment with tepotinib.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14247W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6909.97	31.60	Tecentriq SC [RO]

**ATEZOLIZUMAB**
**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**10206**

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be previously untreated, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14248X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6909.97	31.60	Tecentriq SC [RO]

**ATEZOLIZUMAB**
**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
**15455**

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

Treatment Phase: 1,875 mg administered once every 3 weeks

**Population criteria:**

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR
- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

**Clinical criteria:**

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14269B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	6909.97	31.60	Tecentriq SC [RO]

## ■ ATEZOLIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**10917**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

#### **Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have developed disease progression while being treated with this drug for this condition.
- PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

### **atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14566P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	6909.97	31.60	Tecentriq SC [RO]

## ■ ATEZOLIZUMAB

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**13448**

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment 1

#### **Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

#### **Clinical criteria:**

- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting; OR
- The condition must have progressed after treatment with tepotinib, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

### Authority required (STREAMLINED)

**10125**

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment 2

#### **Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

#### **Clinical criteria:**

- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.

### **atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14266W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6909.97	31.60	Tecentriq SC [RO]

## ■ ATEZOLIZUMAB

**Caution** The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

## **Authority required (STREAMLINED)**

**10939**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

### **Clinical criteria:**

- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

## **atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14278L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6909.97	31.60	Tecentriq SC [RO]

## OTHER ANTINEOPLASTIC AGENTS

### *Histone deacetylase (HDAC) inhibitors*

#### ▪ VORINOSTAT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

## **Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have received systemic treatment with chemotherapy, **AND**
  - Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
  - Patient must be ineligible for stem cell transplant, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

## **vorinostat 100 mg capsule, 120**

11138F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4249.61	31.60	Zolinza [MK]

#### ▪ VORINOSTAT

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

## **Authority required**

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**vorinostat 100 mg capsule, 120**

11141J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4249.61	31.60	Zolinza [MK]

**Hedgehog pathway inhibitors**

▪ **SONIDEGB**

**Caution** Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)).

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

## **Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

## **Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## **Authority required**

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### sonidegib 200 mg capsule, 30

11304Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7592.96	31.60	Odomzo [RA]

### ■ VISMODEGIB

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and
- (c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### **Inappropriate for surgery is defined as:**

- (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- (iii) Medical contraindication to surgery.

#### **Inappropriate for curative radiotherapy is defined as:**

- (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- (ii) Limitations due to location of tumour; or
- (iii) Limitations due to cumulative prior radiotherapy dose; or
- (iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

#### Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### vismodegib 150 mg capsule, 28

11070P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7097.60	31.60	Erivedge [RO]

### *Poly (ADP-ribose) polymerase (PARP) inhibitors*

#### ■ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

#### **Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg tablet, 84

14173Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9874.86	31.60	Zejula [GK]

#### ■ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

#### **Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg tablet, 84

14190W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9874.86	31.60	Zejula [GK]

#### ■ NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

#### **Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg tablet, 56

14196E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6637.44	31.60	Zejula [GK]

## NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

### Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg tablet, 56

14206Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6637.44	31.60	Zejula [GK]

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

### Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; **OR**
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

### Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

### niraparib 100 mg tablet, 56

14172X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6637.44	31.60	Zejula [GK]

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

#### Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

#### Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

#### niraparib 100 mg tablet, 56

14179G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6637.44	31.60	Zejula [GK]

### ■ NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

#### Note Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

#### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

#### Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

#### Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

#### niraparib 100 mg tablet, 84

14207R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9874.86	31.60	Zejula [GK]

### ■ NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

#### Note Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

**Clinical criteria:**

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; **OR**
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

**niraparib 100 mg tablet, 84**

14212B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9874.86	31.60	Zejula [GK]

**■ OLAPARIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****14760**

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of subsequent-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial subsequent-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

**olaparib 100 mg tablet, 56**

11503K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

11539H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**■ OLAPARIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**olaparib 100 mg tablet, 56**

12169L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

12161C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**■ OLAPARIB**
**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**olaparib 100 mg tablet, 56**

11522K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

11528R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6632.11	31.60	Lynparza [AP]

**■ OLAPARIB**
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

**olaparib 100 mg tablet, 56**

12921C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

12913P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Special Pricing Arrangements apply.

### Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

### Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

### Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time.

### olaparib 100 mg tablet, 56

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

### olaparib 150 mg tablet, 56

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

## OLAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation)

### Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

### Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
  - Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.
- A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.
- Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

### olaparib 100 mg tablet, 56

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

### olaparib 150 mg tablet, 56

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	2	..	*6632.11	31.60	Lynparza [AP]

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**olaparib 100 mg tablet, 56**

13782J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

13807Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**■ OLAPARIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Early breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug as adjuvant therapy for this condition, **AND**
- Patient must not have developed disease recurrence while receiving treatment with this drug for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit beyond a total of 52 weeks of treatment (including any non-PBS-subsidised supply), **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.

**olaparib 100 mg tablet, 56**

14216F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	6	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

14215E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	6	..	*6632.11	31.60	Lynparza [AP]

**■ OLAPARIB**

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Early breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must have received neoadjuvant or adjuvant chemotherapy, **AND**
- The treatment must be adjuvant to surgical resection, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant, **AND**
- Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); OR
- Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; OR
- Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes, **AND**
- The treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/(ii) has occurred, **AND**

- The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy, **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.

Retain all pathology imaging and investigative test results in the patient's medical records.

Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).

#### olaparib 100 mg tablet, 56

14181J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

#### olaparib 150 mg tablet, 56

14208T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

### ■ OLAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

#### Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

#### Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

#### olaparib 100 mg tablet, 56

13783K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6632.11	31.60	Lynparza [AP]

#### olaparib 150 mg tablet, 56

13800H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6632.11	31.60	Lynparza [AP]

### ■ OLAPARIB

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required



Metastatic breast cancer  
Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
  - The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant, **AND**
  - Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
  - Patient must have received chemotherapy in the neoadjuvant, adjuvant or metastatic setting, **AND**
  - Patient must not have received PBS-subsidised treatment with this drug in any earlier line of treatment for breast cancer, **AND**
  - The condition must be triple negative breast cancer; OR
  - The condition must be hormone-receptor positive breast cancer and the patient has either: (i) progressive disease after receiving endocrine therapy, (ii) been considered inappropriate for endocrine therapy, **AND**
  - The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.
- Retain all pathology imaging and investigative test results in the patient's medical records. Do not submit copies of these as part of the authority application.

Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).

**Authority required**

Metastatic breast cancer  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug in the metastatic setting, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**olaparib 100 mg tablet, 56**

14689D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

**olaparib 150 mg tablet, 56**

14687B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6632.11	31.60	Lynparza [AP]

■ **TALAZOPARIB**

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must not have received prior PBS-subsidised novel hormonal drug in any non-metastatic setting of prostate cancer prior to commencing treatment with this drug for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance score no higher than 1 prior to treatment initiation, **AND**
- Patient must be undergoing concurrent treatment with enzalutamide, unless an intolerance to enzalutamide requires either a: (i) temporary cessation, (ii) permanent discontinuation, **AND**
- The treatment must not be a PBS-subsidised benefit beyond disease progression.

**talazoparib 250 microgram capsule, 30**

14684W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3628.40	31.60	Talzenna [PF]

**talazoparib 500 microgram capsule, 30**

14683T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3628.40	31.60	Talzenna [PF]

**talazoparib 350 microgram capsule, 30**

14690E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3628.40	31.60	Talzenna [PF]

**talazoparib 100 microgram capsule, 30**

14685X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3628.40	31.60	Talzenna [PF]

**Other antineoplastic agents**
**■ BELZUTIFAN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Von Hippel-Lindau (VHL) disease

Treatment Phase: Initiating or recommencing treatment

**Clinical criteria:**

- The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL, **AND**
- The condition must be at least one of: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET), **AND**
- Patient must not have tumour(s) that require immediate surgery as assessed by the treating clinician, **AND**
- Patient must be untreated with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for a different tumour type; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition and ceased previous treatment for family planning purposes, **AND**
- Patient must have WHO performance status no higher than 1; OR
- The condition must be VHL-associated brainstem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to:

- (i) retinal, spinal, or cerebellar haemangioblastoma;
- (ii) adrenal or extra-adrenal pheochromocytoma;
- (iii) renal cell carcinoma;
- (iv) multiple renal and pancreatic cysts;
- (v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.

**Authority required**

Von Hippel-Lindau (VHL) disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same tumour type, **AND**
- Patient must not have developed VHL-associated metastatic disease, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of the condition while being treated with this drug, the details of which must be kept with the patient's record, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to:

- (i) avoidance of surgery;
- (ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL - associated renal cell carcinoma (RCC);
- (iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).

**Authority required**

Von Hippel-Lindau (VHL) disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2024, **AND**
- The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL, **AND**
- The condition must have been at least one of the following prior to non-PBS-subsidised treatment with this drug: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET), **AND**
- Patient must not have had tumour(s) that require immediate surgery as assessed by the treating clinician prior to non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; OR
- The condition must have been VHL-associated brain stem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1 at treatment initiation with this drug, **AND**
- Patient must not have developed VHL-associated metastatic disease, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of the condition, the details of which must be kept with the patient's record. This should be assessed only after a total of 6 months of therapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of VHL disease associated tumours. Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to:

- (i) retinal, spinal, or cerebellar haemangioblastoma;
- (ii) adrenal or extra-adrenal pheochromocytoma;
- (iii) renal cell carcinoma;
- (iv) multiple renal and pancreatic cysts;
- (v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.

For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to:

- (i) avoidance of surgery;
- (ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL - associated renal cell carcinoma (RCC);
- (iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**belzutifan 40 mg tablet, 90**

14665W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	22222.60	31.60	Welireg [MK]

**■ HYDROXYCARBAMIDE (HYDROXYUREA)**
**hydroxycarbamide (hydroxyurea) 500 mg capsule, 100**

3093T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	47.78	31.60	<sup>a</sup> Hydrea [LM]	<sup>a</sup> HYDROXYCARBAMIDE MEDSURGE [DZ]

**■ VENETOCLAX**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment under this restriction with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

11639N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7404.47	31.60	Venclexta [VE]

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

### Clinical criteria:

- The treatment must be for dose titration purposes.

### venetoclax 50 mg tablet, 7

11648C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	244.46	31.60	Venclexta [VE]

### venetoclax 10 mg tablet, 2

12999E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	7	..	..	*104.29	31.60	Venclexta [VE]

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy

### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).

### venetoclax 100 mg tablet, 120

12199C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7404.47	31.60	Venclexta [VE]

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy

### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

### venetoclax 100 mg tablet, 120

12205J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7404.47	31.60	Venclexta [VE]

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 5 to 9 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

**venetoclax 100 mg tablet, 120**

14585P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7404.47	31.60	Venclexta [VE]

▪ **VENETOCLAX**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 10 to 15 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

14595E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7404.47	31.60	Venclexta [VE]

▪ **VENETOCLAX**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

**Clinical criteria:**

- The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis), **AND**
- Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug, **AND**
- The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses), **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

**venetoclax 50 mg tablet, 7**

12773G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*952.47	31.60	Venclexta [VE]

**venetoclax 100 mg tablet, 120**

12803W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	7404.47	31.60	Venclexta [VE]

▪ **VENETOCLAX**

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and  
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.  
See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Dose titration for relapsed/refractory disease

#### Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

#### Treatment criteria:

- Patient must not be undergoing retreatment with this drug where any of: (i) prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition.

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

11630D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1706.50	31.60	Venclexta [VE]

### ■ VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and  
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.  
See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)

#### Clinical criteria:

- The condition must be untreated with drug treatment at the time of the first dose of this drug; OR
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

12188L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1706.50	31.60	Venclexta [VE]

### ■ VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and  
(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.  
See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy with ibrutinib - Dose titration (cycle 4)

#### **Clinical criteria:**

- The condition must be untreated with venetoclax at the time of the first dose of this drug, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses).

#### **venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

14584N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1706.50	31.60	Venclexta [VE]

### ■ VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### **Authority required**

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply of first-line therapy

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with ibrutinib for this condition prior to 1 October 2024, **AND**
- Patient must not have developed disease progression while receiving treatment for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the next relevant treatment phase.

A patient may also qualify for treatment under this listing if they have previously received non-PBS-subsidised treatment with venetoclax for this condition prior to 1 October 2024 from Cycle 4.

#### **venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

14599J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1706.50	31.60	Venclexta [VE]

#### **venetoclax 100 mg tablet, 120**

14581K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7404.47	31.60	Venclexta [VE]

## ■ ENDOCRINE THERAPY

### HORMONES AND RELATED AGENTS

#### Progestogens

### ■ MEDROXYPROGESTERONE

#### **Restricted benefit**

Breast cancer

#### **Clinical criteria:**

- The condition must be hormone receptor positive.

#### **Restricted benefit**

Endometrial cancer

**medroxyprogesterone acetate 100 mg tablet, 100**

2725K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	86.39	31.60	Provera [PF]

**medroxyprogesterone acetate 200 mg tablet, 60**

2316X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	96.64	31.60	Provera [PF]

**medroxyprogesterone acetate 250 mg tablet, 60**

2727M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	99.16	31.60	Provera [PF]

■ **MEDROXYPROGESTERONE****Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**Restricted benefit**

Endometrial cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**medroxyprogesterone acetate 100 mg tablet, 100**

14067J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*161.61	31.60	Provera [PF]

**medroxyprogesterone acetate 200 mg tablet, 60**

13881N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*183.13	31.60	Provera [PF]

**medroxyprogesterone acetate 250 mg tablet, 60**

13961T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*188.43	31.60	Provera [PF]

*Gonadotropin releasing hormone analogues*■ **GOSERELIN****Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**goserelin 10.8 mg implant, 1**

8093Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	714.56	31.60	Zoladex 10.8 Implant [AP]

■ **GOSERELIN****Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

**Restricted benefit**

Endometriosis

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

**Note** Only 1 course of not more than 6 months' therapy will be authorised.**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.



**Restricted benefit**

Anticipated premature ovarian failure

**Clinical criteria:**

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

**Population criteria:**

- Patient must be pre-menopausal.

**goserelin 3.6 mg implant, 1**

1454M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	213.17	31.60	Zoladex Implant [AP]

**■ GOSERELIN (&) BICALUTAMIDE**
**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28], 1 pack**

9065D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1043.25	31.60	ZolaCos CP 10.8/50(28) [AP]

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84], 1 pack**

9066E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1322.92	31.60	ZolaCos CP 10.8/50(84) [AP]

**goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack**

9064C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	413.71	31.60	ZolaCos CP 3.6/50 [AP]

**■ LEUPRORELIN**
**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**leuprorelin acetate 45 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11943N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1377.18	31.60	Lucrin Depot 6-Month [VE]

**leuprorelin acetate 22.5 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

8876E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	714.56	31.60	Lucrin Depot 3 Month PDS [VE]

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

8877F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	940.53	31.60	Lucrin Depot 4 Month PDS [VE]

**leuprorelin acetate 7.5 mg modified release injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber syringe**

8875D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	271.00	31.60	Lucrin Depot 7.5mg PDS [VE]

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8708H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	714.56	31.60	Eligard 3 month [MF]

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8709J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	940.53	31.60	Eligard 4 month [MF]

**leuporelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8859G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1377.18	31.60	Eligard 6 month [MF]

**leuporelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

8707G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	271.00	31.60	Eligard 1 month [MF]

▪ **LEUPORELIN****Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuporelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11944P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	713.72	31.60	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ **LEUPORELIN****Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10<sup>th</sup> birthday if female; OR
- Patient must be of an age that is prior to their 11<sup>th</sup> birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8<sup>th</sup> birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9<sup>th</sup> birthday if male.

**leuporelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

11960L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	713.72	31.60	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ **LEUPORELIN****Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10<sup>th</sup> birthday if female; OR
- Patient must be of an age that is prior to their 11<sup>th</sup> birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8<sup>th</sup> birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9<sup>th</sup> birthday if male.

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuporelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

13187C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1377.18	31.60	Eligard 6 month [MF]

▪ **LEUPORELIN (&) BICALUTAMIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**leuporelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10962Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	417.76	31.60	Bi ELIGARD CP [MF]

**leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

10963B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	976.71	31.60	Bi ELIGARD CP [MF]

**leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

10969H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1109.71	31.60	Bi ELIGARD CP [MF]

▪ **TRIPTORELIN**

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

9379P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	714.66	31.60	Diphereline [IS]

**triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

9378N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	271.04	31.60	Diphereline [IS]

▪ **TRIPTORELIN**

**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 12<sup>th</sup> birthday if female; OR
- Patient must be of an age that is prior to their 13<sup>th</sup> birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9<sup>th</sup> birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10<sup>th</sup> birthday if male.

**Restricted benefit**

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

5297T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1377.24	31.60	Diphereline [IS]

**HORMONE ANTAGONISTS AND RELATED AGENTS****Anti-estrogens****■ FULVESTRANT****Authority required (STREAMLINED)****11473**

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable.

**Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes**

12300J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	160.42	31.60	<sup>a</sup> FULVESTRANT ACCORD [OC] <sup>a</sup> FULVESTRANT EVER PHARMA [IT]	<sup>a</sup> FULVESTRANT-AFT [AE] <sup>a</sup> Fulvestrant Sandoz [SZ]

**■ TAMOXIFEN**

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

1880Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	<sup>B</sup> 5.52	*29.67	25.60	<sup>a</sup> Nolvadex-D [AP]

**■ TAMOXIFEN**

**Note** For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

13960R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	<sup>B</sup> 11.04	*45.87	31.60	<sup>a</sup> Nolvadex-D [AP]

**■ TAMOXIFEN**

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 60**

2110C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	24.15	25.60	<sup>a</sup> Genox 20 [AF] <sup>a</sup> Tamosin [OX]	<sup>a</sup> GenRx Tamoxifen [GX] <sup>a</sup> Tamoxifen Sandoz [SZ]

## ■ TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

### Restricted benefit

Breast cancer

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### tamoxifen 20 mg tablet, 60

13997Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.85	31.60	<sup>a</sup> Genox 20 [AF]	<sup>a</sup> GenRx Tamoxifen [GX]
						<sup>a</sup> Tamosin [OX]	<sup>a</sup> Tamoxifen Sandoz [SZ]

## ■ TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Reduction of breast cancer risk

### Clinical criteria:

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

### tamoxifen 20 mg tablet, 30

10911G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.80	20.25	<sup>a</sup> Genox 20 [AF]
			<sup>B</sup> 2.76	21.56	20.25	<sup>a</sup> Nolvadex-D [AP]

## ■ TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Reduction of breast cancer risk

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

### tamoxifen 20 mg tablet, 30

13906X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.15	25.60	<sup>a</sup> Genox 20 [AF]
			<sup>B</sup> 5.52	*29.67	25.60	<sup>a</sup> Nolvadex-D [AP]

## ■ TOREMIFENE

### toremifene 60 mg tablet, 30

8216K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.12	31.60	Fareston [OX]

## ■ TOREMIFENE

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## toremifene 60 mg tablet, 30

13859K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*90.79	31.60	Fareston [OX]

### Anti-androgens

## ■ APALUTAMIDE

**Note** Special Pricing Arrangements apply.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

### Authority required

Castration resistant non-metastatic carcinoma of the prostate

### Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

### Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

## apalutamide 60 mg tablet, 120

12992T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3715.90	31.60	Erlyand [JC]

## ■ APALUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Metastatic castration sensitive carcinoma of the prostate

### Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

### Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

## apalutamide 60 mg tablet, 120

13288J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3715.90	31.60	Erlyand [JC]

## ■ BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**5729**

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**bicalutamide 50 mg tablet, 28**

8094B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.54	31.60	<sup>a</sup> APO-Bicalutamide [TX]	<sup>a</sup> Bicalox [ZS]
						<sup>a</sup> Calutex [AS]	<sup>a</sup> Cosamide 50 [AF]
						<sup>a</sup> Cosudex [AP]	

**■ CYPROTERONE**
**cypoterone acetate 100 mg tablet, 50**

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	61.27	31.60	<sup>a</sup> ANTERONE 100 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 1.21	62.48	31.60	<sup>a</sup> Androcur-100 [GH]	

**cypoterone acetate 50 mg tablet, 50**

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*74.87	31.60	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 1.96	*76.83	31.60	<sup>a</sup> Androcur [GH]	

**■ CYPROTERONE**
**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**cypoterone acetate 100 mg tablet, 50**

14022B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*109.09	31.60	<sup>a</sup> ANTERONE 100 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 2.42	*111.51	31.60	<sup>a</sup> Androcur-100 [GH]	

**cypoterone acetate 50 mg tablet, 50**

14023C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*137.39	31.60	<sup>a</sup> ANTERONE 50 [RW]	<sup>a</sup> Cyproterone Sandoz [HX]
			<sup>B</sup> 4.12	*141.51	31.60	<sup>a</sup> Androcur [GH]	

**■ DAROLUTAMIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

**Prescribing instructions:**

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**darolutamide 300 mg tablet, 112**

12684N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3538.24	31.60	Nubeqa [BN]

**■ DAROLUTAMIDE**

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**darolutamide 300 mg tablet, 112**

13769Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3538.24	31.60	Nubeqa [BN]

**■ ENZALUTAMIDE**

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; OR
- Patient must have been receiving PBS-subsidised treatment with abiraterone or abiraterone plus methylprednisolone for castration resistant metastatic prostate cancer prior to being associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation.

**enzalutamide 40 mg capsule, 112**

10174L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3313.23	31.60	Xtandi [LL]

**■ ENZALUTAMIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**



- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

**Prescribing instructions:**

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**enzalutamide 40 mg capsule, 112**

13118K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3313.23	31.60	Xtandi [LL]

**■ ENZALUTAMIDE**

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**enzalutamide 40 mg capsule, 112**

13353T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3313.23	31.60	Xtandi [LL]

**■ FLUTAMIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**5729**

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 100**

1417N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	175.70	31.60	Flutamin [AF]

NP

**Aromatase inhibitors**
**■ ANASTROZOLE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

8179L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.27	22.72	<sup>a</sup> Anastrozole GH [GQ] <sup>a</sup> ANASTROZOLE-WGR [WG] <sup>a</sup> Arianna 1 [AF]	<sup>a</sup> Anastrozole Sandoz [SZ] <sup>a</sup> APO-Anastrozole [TX]

■ **ANASTROZOLE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

1385J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*29.09	30.54	<sup>a</sup> Anastrozole GH [GQ] <sup>a</sup> ANASTROZOLE-WGR [WG] <sup>a</sup> Arianna 1 [AF]	<sup>a</sup> Anastrozole Sandoz [SZ] <sup>a</sup> APO-Anastrozole [TX]

■ **EXEMESTANE****Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**exemestane 25 mg tablet, 30**

10103R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	51.30	31.60	<sup>a</sup> APO-Exemestane [TX] <sup>a</sup> Exemestane Sandoz [SZ] <sup>a</sup> Aromasin [PF]	<sup>a</sup> Exemestane GH [GQ] <sup>a</sup> EXEMESTANE-WGR [WG]
			<sup>B</sup> 2.73	54.03	31.60		

■ **EXEMESTANE****Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**exemestane 25 mg tablet, 30**

14036R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*89.15	31.60	<sup>a</sup> APO-Exemestane [TX] <sup>a</sup> Exemestane Sandoz [SZ] <sup>a</sup> Aromasin [PF]	<sup>a</sup> Exemestane GH [GQ] <sup>a</sup> EXEMESTANE-WGR [WG]
			<sup>B</sup> 5.46	*94.61	31.60		

■ **EXEMESTANE**

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Restricted benefit**

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

### exemestane 25 mg tablet, 30

8506Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.30	31.60	<sup>a</sup> APO-Exemestane [TX]	<sup>a</sup> Exemestane GH [GQ]
						<sup>a</sup> Exemestane Sandoz [SZ]	<sup>a</sup> EXEMESTANE-WGR [WG]
			<sup>B</sup> 2.73	54.03	31.60	<sup>a</sup> Aromasin [PF]	

## EXEMESTANE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

### Restricted benefit

Breast cancer

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### exemestane 25 mg tablet, 30

13857H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*89.15	31.60	<sup>a</sup> APO-Exemestane [TX]	<sup>a</sup> Exemestane GH [GQ]
						<sup>a</sup> Exemestane Sandoz [SZ]	<sup>a</sup> EXEMESTANE-WGR [WG]
			<sup>B</sup> 5.46	*94.61	31.60	<sup>a</sup> Aromasin [PF]	

## LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

### Restricted benefit

Breast cancer

### Clinical criteria:

- The condition must be hormone receptor positive.

### letrozole 2.5 mg tablet, 30

8245Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.91	25.36	<sup>a</sup> ARX-LETROZOLE [XT]	<sup>a</sup> Femolet [AF]
						<sup>a</sup> Gynotril [ZS]	<sup>a</sup> Letrozole APOTEX [GX]
						<sup>a</sup> Letrozole GH [HQ]	<sup>a</sup> Letrozole Sandoz [SZ]
						<sup>a</sup> LETROZOLE-WGR [WG]	<sup>a</sup> Pharmacor Letrozole 2.5 [CR]
			<sup>B</sup> 5.00	28.91	25.36	<sup>a</sup> Femara 2.5 mg [NV]	

## LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

### Restricted benefit

Breast cancer

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### letrozole 2.5 mg tablet, 30

13939P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.37	31.60	<sup>a</sup> ARX-LETROZOLE [XT]	<sup>a</sup> Femolet [AF]
						<sup>a</sup> Gynotril [ZS]	<sup>a</sup> Letrozole APOTEX [GX]
						<sup>a</sup> Letrozole GH [HQ]	<sup>a</sup> Letrozole Sandoz [SZ]
						<sup>a</sup> LETROZOLE-WGR [WG]	<sup>a</sup> Pharmacor Letrozole 2.5 [CR]
			<sup>B</sup> 10.00	*44.37	31.60	<sup>a</sup> Femara 2.5 mg [NV]	

### Other hormone antagonists and related agents

## ABIRATERONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 250 mg tablet, 120**

2698B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	985.55	31.60	<sup>a</sup> Abiraterone Sandoz [SZ] <sup>a</sup> Zytiga [JC]	<sup>a</sup> Abiraterone-Teva [TB]

**abiraterone acetate 500 mg tablet, 60**

11206T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	985.55	31.60	<sup>a</sup> Abiraterone Sandoz [SZ] <sup>a</sup> Zytiga [JC]	<sup>a</sup> Abiraterone-Teva [TB]

▪ **ABIRATERONE (&) METHYLPREDNISOLONE**

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

13263C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	987.95	31.60	Yonsa Mpred [RA]

▪ **ABIRATERONE (&) METHYLPREDNISOLONE**

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack**

14078Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	834.68	31.60	Yonsa Mpred [RA]

▪ **DEGARELIX**

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

2784M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	363.78	31.60	Firmagon 80mg [FP]

▪ **DEGARELIX**

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack**

2785N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	380.39	31.60	Firmagon 120mg [FP]

▪ **IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

*Interferons*

▪ **INTERFERON BETA-1B**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**16321**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**16297**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack**

8101J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	763.54	31.60	Betaferon [BN]

NP

## ■ PEGINTERFERON ALFA-2A

### peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11416W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	543.04	31.60	Pegasys [XO]

### peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11037X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	627.54	31.60	Pegasys [XO]

## ■ PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**16321**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

#### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

### peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10212L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	4	..	635.56	31.60	Plegridy [BD]

### peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack

10218T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	±1	..	..	635.56	31.60	Plegridy [BD]

## ■ PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**16297**

Multiple sclerosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

#### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

### peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10220X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	635.56	31.60	Plegridy [BD]

### *Other immunostimulants*

## ■ GLATIRAMER ACETATE

**Note** Pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL syringes and pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**16321**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)****16297**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices**

13110B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	598.86	31.60	<sup>a</sup> Copaxone [TB]

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes**

10416F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	563.52	31.60	<sup>a</sup> Copaxone [TB] <sup>a</sup> GLATIRAMER ACETATE-TEVA [EV]	<sup>a</sup> Glatira [JU]

**■ MYCOBACTERIUM BOVIS BCG DANISH STRAIN****Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials**

12931N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±3	1	..	*1797.81	31.60	VesiCulture [LM]

**■ MYCOBACTERIUM BOVIS BCG TICE STRAIN****Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials**

1131M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	459.47	31.60	OncoTICE [MK]

**■ IMMUNOSUPPRESSANTS****IMMUNOSUPPRESSANTS***Selective immunosuppressants***■ ABATACEPT****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be

subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of



more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

##### **14604**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

#### **abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

13727L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	946.96	31.60	Orencia ClickJect [BQ]

#### **abatacept 125 mg/mL injection, 4 x 1 mL syringes**

13726K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	946.96	31.60	Orencia [BQ]

### ▪ ABATACEPT

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

11684Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	946.96	31.60	Orencia ClickJect [BQ]

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1221G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	946.96	31.60	Orencia [BQ]

**■ ABATACEPT****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- a total active joint count of at least 20 active (swollen and tender) joints; or
- at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application.

The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

11693K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	946.96	31.60	Orencia ClickJect [BQ]



**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	946.96	31.60	Orencia [BQ]

**APREMILAST**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**15326**

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

**Population criteria:**

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**apremilast 30 mg tablet, 56**

12223H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	654.18	31.60	Otezla [AN]

**apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27**

12218C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	273.67	31.60	Otezla [AN]

**CLADRIBINE**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16345**

Relapsing remitting multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product

Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**Authority required (STREAMLINED)**

**16299**

Relapsing remitting multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**cladribine 10 mg tablet, 6**

11611D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22010.94	31.60	Mavenclad [SG]

**cladribine 10 mg tablet, 1**

11603Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	3803.99	31.60	Mavenclad [SG]

**cladribine 10 mg tablet, 4**

11604R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	1	..	*29293.73	31.60	Mavenclad [SG]

■ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**mycophenolate mofetil 250 mg capsule, 100**

8649F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*95.67	31.60	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]	<sup>a</sup> Mycophenolate Sandoz [SZ]

**mycophenolate 180 mg enteric tablet, 120**

2150E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	105.70	31.60	<sup>a</sup> Mycophenolic Acid ARX [XT]	<sup>a</sup> Myfortic [NV]

**mycophenolate 360 mg enteric tablet, 120**

2193K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	202.14	31.60	<sup>a</sup> Mycophenolic Acid ARX [XT] <sup>a</sup> Myfortic [NV]	<sup>a</sup> MYCOTEX [CR]

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

8651H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	#287.67	31.60	<sup>a</sup> CellCept [RO]	<sup>a</sup> Pharmacor Mycophenolate [CR]

**mycophenolate mofetil 500 mg tablet, 50**

8650G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*95.58	31.60	<sup>a</sup> ARX-MYCOPHENOLATE [XT] <sup>a</sup> MycoCept [RF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate GH [GQ] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

■ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mycophenolate mofetil 250 mg capsule, 100**

13884R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*181.11	31.60	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]	<sup>a</sup> Mycophenolate Sandoz [SZ]

**mycophenolate 180 mg enteric tablet, 120**

13856G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*202.17	31.60	<sup>a</sup> Mycophenolic Acid ARX [XT]	<sup>a</sup> Myfortic [NV]

**mycophenolate 360 mg enteric tablet, 120**

13938N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*395.83	31.60	<sup>a</sup> Mycophenolic Acid ARX [XT] <sup>a</sup> Myfortic [NV]	<sup>a</sup> MYCOTEX [CR]

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

14071N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*#563.71	31.60	<sup>a</sup> CellCept [RO]	<sup>a</sup> Pharmacor Mycophenolate [CR]

**mycophenolate mofetil 500 mg tablet, 50**

14000W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*180.87	31.60	<sup>a</sup> ARX-MYCOPHENOLATE [XT] <sup>a</sup> MycoCept [RF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate GH [GQ] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

*Tumor necrosis factor alpha (TNF-alpha) inhibitors*

▪ **ADALIMUMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
  - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
  - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a

severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12379M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10399H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12411F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10400J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15445**

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14234E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14262P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

■ **ADALIMUMAB**

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14242N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14263Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

■ **ADALIMUMAB**

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**15445**

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14629Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

14243P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14586Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

14283R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**15445**

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14751J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

14772L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

## ■ ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:



Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**11529**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

#### **adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

14587R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	<sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Yuflyma [EW]

#### **adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

14622N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	Yuflyma [EW]

## ■ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12413H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10412B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

## (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

## (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12341M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10420K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- the patient has never been prescribed the newly listed biological medicine; and
- the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

- Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**11631**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13225C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12352D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline



measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**11524**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13230H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12353E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
  - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

#### **11604**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13209F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12365T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**11524**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum of 24 weeks treatment will be authorised under this restriction.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13220T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12367X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

## **Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12389C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9191R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
  - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

#### **11604**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**



- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13223Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12401Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

- (a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for

this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### Authority required

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12410E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11523

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13214L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12415K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreat of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 6 to 17 years inclusive.

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13224B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12420Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with

respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 6 to 17 years inclusive.

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13218Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12434K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different



pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**11631**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13219R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12437N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**11523**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13216N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12438P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

### Authority required

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

### Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14777R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

14245R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	649.05	31.60	<sup>a</sup> Humira [VE]

### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

14749G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

## ■ ADALIMUMAB

### **Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11529

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

#### Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13221W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*979.13	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12330Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
- a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised

therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14252D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12423W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	649.05	31.60	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12354F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

**■ ADALIMUMAB**
**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years), or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12449F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*1346.05	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12395J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*1346.05	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB****Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing



treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 6 to 17 years inclusive.

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PCDAI assessment must be no more than 4 weeks old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14274G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

#### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12436M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted

no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

11579

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13213K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12325Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

### (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required (STREAMLINED)**

#### **11579**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6

to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13211H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12334E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**11635**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.
- An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

**11606**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13217P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12366W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a



treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

#### (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

#### (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy

of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

##### **11635**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

##### **11606**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13215M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR]	<sup>a</sup> Hadlima [RF]
						<sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Yuflyma [EW]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12403T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF]	<sup>a</sup> Amgevita [XT]

## ■ ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least

5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

12423N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

#### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12424X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	649.05	31.60	<sup>a</sup> Humira [VE]

#### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12440R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab

only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

#### (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**11579**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14253E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12351C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

**■ ADALIMUMAB****Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years), or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

#### Treatment criteria:

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12383R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*979.13	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12385W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*1108.87	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:



**(1) Initial treatment.**

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

**(2) Grandfather patients (secukinumab only).**

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

**(3) Continuing treatment.**

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

**(4) Changing/swapping therapy.**

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

**(5) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12448E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12408C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13222X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12326R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID

therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14683**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

**14701**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or  
 (b) a CRP measurement no greater than 10 mg per L; or  
 (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13208E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12327T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot

change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14683**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

**14701**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13226D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12328W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application



following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13227E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12329X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24

weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12399N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5283C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be

in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12425Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]



**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

5284D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14567**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13703F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

13686H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14567**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13732R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

13721E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### **■ ADALIMUMAB**

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

#### Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

#### Authority required

Vision threatening non-infectious uveitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024, **AND**
- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent prior to commencing non-PBS-subsidised treatment; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; OR
- Patient must have failed to achieve an adequate response to prior conventional immunomodulatory therapy in patients for whom corticosteroids are not clinically appropriate prior to commencing non-PBS-subsidised treatment; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy prior to commencing non-PBS-subsidised treatment, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment with this drug for this condition if they have received more than 25 weeks of non-PBS-subsidised treatment, **AND**
- The treatment must not exceed 24 weeks under this restriction.

#### Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14221L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14261N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024, **AND**
- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent prior to commencing non-PBS-subsidised treatment; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; OR
- Patient must have failed to achieve an adequate response to prior conventional immunomodulatory therapy in patients for whom corticosteroids are not clinically appropriate prior to commencing non-PBS-subsidised treatment; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy prior to commencing non-PBS-subsidised treatment,

**AND**

- Patient must have demonstrated or sustained an adequate response to treatment with this drug for this condition if they have received more than 25 weeks of non-PBS-subsidised treatment, **AND**
- The treatment must not exceed 24 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

- (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or
- (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or
- (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14591Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

14251C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

#### Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

#### Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

#### Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12414J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*979.13	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12369B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]



## ■ ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy

of less than 5 years ) [further details are under 'Swapping treatment' below]; or  
 (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or  
 (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response. For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

#### (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12391E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF]	<sup>a</sup> Humira [VE]

<sup>a</sup> Hyrimoz [SZ]

<sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10960W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
  - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
- Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12358K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10961X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

#### Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

#### Authority required

Vision threatening non-infectious uveitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024, **AND**
- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent prior to commencing non-PBS-subsidised treatment; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; OR
- Patient must have failed to achieve an adequate response to prior conventional immunomodulatory therapy in patients for whom corticosteroids are not clinically appropriate prior to commencing non-PBS-subsidised treatment; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy prior to commencing non-PBS-subsidised treatment, **AND**

#### AND

- Patient must have demonstrated or sustained an adequate response to treatment with this drug for this condition if they have received more than 25 weeks of non-PBS-subsidised treatment, **AND**
- The treatment must not exceed 24 weeks under this restriction.

#### Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

- (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;
- (b) A 2-step increase in anterior chamber cells or vitreous haze;
- (c) New retinal vasculitis;
- (d) New retinal or choroidal lesions;
- (e) Other signs of disease progression including visual field changes or electroretinogram changes

An adequate response to treatment is defined as:

- (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or
- (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or
- (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or
- (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14750H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

#### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

14275H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	649.05	31.60	<sup>a</sup> Humira [VE]

#### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

14747E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

### ■ ADALIMUMAB

#### **Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

- (a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

- (b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

- (c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.



**(d) Continuing treatment**

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

**(e) Balance of supply**

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

**AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12419P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12372E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for

response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14294H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

#### **adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12337H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	649.05	31.60	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12357J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

**■ ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**



- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12361N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9078T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break

in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12363Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9104E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

**(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12375H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9102C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;



AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12390D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9100Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### **■ ADALIMUMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological

medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12398M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF]	<sup>a</sup> Humira [VE]
						<sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9034L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF]	<sup>a</sup> Amgevita [XT]
						<sup>a</sup> Hadlima [RF]	<sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB****Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at

any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy. A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12405X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8964T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

■ **ADALIMUMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.



**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12430F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF]	<sup>a</sup> Humira [VE]

<sup>a</sup> Hyrimoz [SZ]

<sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8741C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A maximum of 24 weeks treatment will be authorised under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12446C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

8966X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; OR
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

#### **Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

- (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;
- (b) A 2-step increase in anterior chamber cells or vitreous haze;
- (c) New retinal vasculitis;
- (d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

- (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or
- (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or
- (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or
- (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) details of the proposed prescription; and
- (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**

- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14628X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	6	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

14222M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	6	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; OR
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

- (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or  
 (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)  
 Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) details of the proposed prescription; and
- (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Commencement of treatment

#### **Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**
- The treatment must not exceed 25 weeks under this restriction.

#### **Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14272E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	6	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14284T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	6	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the

alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy. A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.



**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

- (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
- (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

#### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12360M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12393G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Yuflyma [EW]

### ■ ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreat of conventional therapies is not required.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Requests for quantities/repeats insufficient to complete 16 weeks:**

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12426B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12409D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB**
**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count; and
  - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
  - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12450G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12524E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB**
**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
  - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
  - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.



(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Requests for quantities/repeats insufficient to complete 16 weeks:**

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR
  - Must be treated by a specialist paediatric gastroenterologist.
- The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12373F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12432H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10413C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12388B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised

therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Requests for quantities/repeats insufficient to complete 16 weeks:**

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 6 to 17 years inclusive.

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12338J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12455M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10419J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12416L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

- Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).
- Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution
- Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; OR
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; OR
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

#### **Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

- (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;
- (b) A 2-step increase in anterior chamber cells or vitreous haze;
- (c) New retinal vasculitis;
- (d) New retinal or choroidal lesions;
- (e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

- (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or
- (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or
- (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or
- (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) details of the proposed prescription; and
- (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14764C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

14244Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	649.05	31.60	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

14748F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	6	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

**■ ADALIMUMAB**
**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic



use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

- (i) the Hurley stage grading; and
- (ii) the AN count.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12454L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12356H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

■ **ADALIMUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

**(1) Initial treatment.**

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

**(2) Assessment of response to initial treatment.**

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

### (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

### (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
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Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12377K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9428F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate



biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

## **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

## **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
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Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
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#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12422T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9427E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

### Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

### Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

### Requests for quantities/repeats insufficient to complete 16 weeks:

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

- Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution
- Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PCDAI assessment must be no more than 4 weeks old at the time of application.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14295J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12407B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	649.05	31.60	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12332C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

## ■ ADALIMUMAB

### Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline



measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

#### **Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12340L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12381P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12386X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

8965W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be at least 18 years of age.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

#### **Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

#### AND

- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### Prescribing the 40 mg presentation:

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

#### Prescribing the 80 mg presentation:

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12345R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12433J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12402R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9190Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB**
**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:



- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

# **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

## **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

# **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12364R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5281Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abriada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to

Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or

- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12428D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

5282B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### **ADALIMUMAB**

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under



Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
 (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of results;
- (b) details of prior treatment, including dose and date/duration of treatment.
- (c) If applicable, details of any contraindications/intolerances.
- (d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of result;
- (b) the most recent biological agent and the date of the last continuing prescription.
- (c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13691N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

13692P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### **■ ADALIMUMAB**

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must

be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of results;
- (b) details of prior treatment, including dose and date/duration of treatment.
- (c) If applicable, details of any contraindications/intolerances.
- (d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of result;
- (b) the most recent biological agent and the date of the last continuing prescription.
- (c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13704G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13722F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).



Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and
- (iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13763J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13744J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and
- (iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13764K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

13754X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks

following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.



Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12380N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12397L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12331B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8963R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

#### Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

#### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12374G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

#### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12339K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*2014.86	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

### ■ ADALIMUMAB

#### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different

pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

#### Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Population criteria:

- Patient must be at least 18 years of age.

#### Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR

- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

#### **Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**



- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**

**AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.
- The authority application must be made in writing and must include:
- (1) two completed authority prescription forms; and
  - (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

One prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Prescribing the 80 mg presentation:**

One prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12451H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12453K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12387Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9188N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate

biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a

parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12362P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9101B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

#### Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that

apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.



The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12376J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9103D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,  
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,  
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12378L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF]	<sup>a</sup> Humira [VE]
						<sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Yuflyma [EW]

#### **adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9033K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF]	<sup>a</sup> Amgevita [XT]
						<sup>a</sup> Hadlima [RF]	<sup>a</sup> Hyrimoz [SZ]

### **ADALIMUMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological

medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.



To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12447D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	677.26	31.60	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hyrimoz [SZ]

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12394H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	677.26	31.60	<sup>a</sup> Humira [VE]	<sup>a</sup> Yuflyma [EW]

**■ ADALIMUMAB**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine

cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be assessed where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online



Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12400P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8737W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**ADALIMUMAB**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine,

'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR

- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**

- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12429E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Adalicip [LR]	<sup>a</sup> Hadlima [RF]

<sup>a</sup> Humira [VE]  
<sup>a</sup> Yuflyma [EW]

<sup>a</sup> Hyrimoz [SZ]

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9099X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abirlada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)



Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
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HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

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#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12442W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9077R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	558.66	31.60	<sup>a</sup> Abilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ ADALIMUMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR

- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

#### Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### Prescribing the 40 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### Prescribing the 80 mg presentation:

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments must be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12359L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12382Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10944B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12333D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abirilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a



treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

### (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

#### Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

- (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12347W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1464.45	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12412G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

10955N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12370C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*1659.06	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

**■ ADALIMUMAB****Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment

cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

**Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).



Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Two completed authority prescriptions should be submitted with every initial application for this biological medicine.

#### **Prescribing the 40 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

#### **Prescribing the 80 mg presentation:**

For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2

doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14273F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	624.52	31.60	<sup>a</sup> Abrilada [PF]

#### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12371D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	649.05	31.60	<sup>a</sup> Humira [VE]

#### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12350B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*624.51	31.60	<sup>a</sup> Amgevita [XT]

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological

medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline

PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) **Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

#### **Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

#### **Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

#### **Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**



- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12342N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	4	..	493.79	31.60	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9426D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	4	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion

of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

#### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

#### **Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**



- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12421R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	4	..	493.79	31.60	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

#### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9425C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	4	..	558.66	31.60	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

### ■ CERTOLIZUMAB PEGOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10892G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11321W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

### ■ CERTOLIZUMAB PEGOL

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

#### Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

#### **AND**

- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10897M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11318Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

## ■ CERTOLIZUMAB PEGOL

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active

joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

#### **AND**

- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10896L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11326D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1027.15	31.60	Cimzia [UC]

### ■ CERTOLIZUMAB PEGOL

#### **Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient'

treatment phase

- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- (iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- (iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

#### (2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

#### (3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

#### (4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

#### (6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

12005W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

12028C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be

measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

#### **AND**

- The treatment must provide no more than the balance of up to 20 weeks treatment.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

12040Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1027.15	31.60	Cimzia [UC]

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

12013G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1027.15	31.60	Cimzia [UC]

### **■ CERTOLIZUMAB PEGOL**

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under



Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

13735X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

13701D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

**■ CERTOLIZUMAB PEGOL**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10137M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11320T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

### ■ CERTOLIZUMAB PEGOL

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an

alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10238W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

#### **certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11324B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

### **■ CERTOLIZUMAB PEGOL**

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP determined with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).



**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

3425G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11325C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1027.15	31.60	Cimzia [UC]

**■ CERTOLIZUMAB PEGOL**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10905Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11322X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

## ■ CERTOLIZUMAB PEGOL

### Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- The following must be provided at the time of application and documented in the patient's medical records:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and  
 (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12063X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

#### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12027B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

### ■ CERTOLIZUMAB PEGOL

#### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2



treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by

- a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
  - Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
  - Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
  - Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
  - Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10904X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11319R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

**■ CERTOLIZUMAB PEGOL****Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10909E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11323Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.99	31.60	Cimzia [UC]

## ■ ETANERCEPT

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting

in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### **Authority required (STREAMLINED)**

##### **9156**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11202N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

#### **etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11216H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]



## ■ ETANERCEPT

### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11197H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

#### ■ ETANERCEPT

##### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11204Q	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

**■ ETANERCEPT**
**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

- (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3448L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

## **■ ETANERCEPT**

### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11201M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11196G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**■ ETANERCEPT**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

- (1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where



prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11218K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11211C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**■ ETANERCEPT**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction

necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 weeks must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14629**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13708L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

13707K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

### ■ ETANERCEPT

#### Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

3450N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

#### **etanercept 50 mg/mL injection, 4 x 1 mL syringes**

3449M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

### **■ ETANERCEPT**

#### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14683**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or

- (b) a CRP measurement no greater than 10 mg per L; or  
 (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

**14701**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or  
 (b) a CRP measurement no greater than 10 mg per L; or  
 (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11215G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

#### **etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11217J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

### ■ ETANERCEPT

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.



Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

#### (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide

new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required (STREAMLINED)**

##### **8887**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

##### **8955**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11221N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

11225T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

### ■ ETANERCEPT

#### Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified from week 12; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

14509

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority required (STREAMLINED)**

**14508**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

13693Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*846.11	31.60	Enbrel [PF]

▪ **ETANERCEPT**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different

biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8638P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for

administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and



(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8779C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

## **■ ETANERCEPT**

### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment.

with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9456Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9086F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ ETANERCEPT

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the

2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9460X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9090K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

## ■ ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active

joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.  
 (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.  
 A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11207W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

**■ ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4



weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs

specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to: Services Australia, Complex Drugs, Reply Paid 9826, HOBART TAS 7001.

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3445H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

#### ■ ETANERCEPT

##### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as:  
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  
either of the following:  
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:  
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  
The authority application must be made in writing and must include:  
(1) a completed authority prescription form(s); and  
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  
Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  
Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  
If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9036N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

#### ■ ETANERCEPT

##### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for

administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**



- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.
- Treatment criteria:**
- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11198J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

11208X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ ETANERCEPT

**Caution** Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighing 62.5kg or more.

#### **Note** TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

- (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

#### (2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

#### (3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

#### (5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

#### (7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase. Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

- (i) the patient's response to treatment can be quantified from week 12; and
- (ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14509**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

#### **Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

#### **Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

#### **Authority required (STREAMLINED)**

**14508**

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

#### **Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

#### **Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

#### **etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

13697X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

#### **etanercept 50 mg/mL injection, 4 x 1 mL syringes**

13733T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

### **■ ETANERCEPT**

#### **Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a

response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline

measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent

course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia

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### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3447K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

3446J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

## ■ ETANERCEPT

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of



therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9458T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9088H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ ETANERCEPT

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide

new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11223Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

**■ ETANERCEPT****Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab,

ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).



**etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack**

9429G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*846.11	31.60	Enbrel [PF]

**■ ETANERCEPT**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11222P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11224R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**■ ETANERCEPT**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

**(1) Initial treatment.**

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### Treatment criteria:

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9462B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9431J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ ETANERCEPT

#### **Note** PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD

treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:



- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of result;
- (b) the most recent biological agent and the date of the last continuing prescription.
- (c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13687J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

13698Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

### ■ ETANERCEPT

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and
- (iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

13774Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

13751R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]

**■ ETANERCEPT**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:



(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8637N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

### ■ ETANERCEPT

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the

most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
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Complex Drugs  
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HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
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HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9459W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9089J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:



After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

- (i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

- (i) all subscores are rated moderate to severe; or
- (ii) 2 of the three subscores are rated severe to very severe; or
- (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

- Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase. Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:
- (i) the patient's response to treatment can be quantified from week 12; and
  - (ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.
- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naïve patient

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) the PASI score that followed each prior therapy trialled;
- (iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or
- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

#### **Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

#### **Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

#### **Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

#### **Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;
- (iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

- (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);
- (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or

- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

#### **Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

#### **Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

### **etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

1954W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

## **■ ETANERCEPT**

### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

#### **Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

#### **(1) Initial treatment.**

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

#### **(2) Grandfather patients (bimekizumab).**

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

#### **(3) Continuing treatment.**

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online



Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
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HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8778B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

### ■ ETANERCEPT

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not

conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9035M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

#### ■ ETANERCEPT

##### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and



(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9455P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9085E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ ETANERCEPT

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a

single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.  
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9457R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9087G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

**ETANERCEPT**

**Caution** Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase. Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

- (i) the patient's response to treatment can be quantified from week 12; and
- (ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naïve patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

- the name of each prior therapy trialled that meets the above requirements - state at least 2;
- the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- the PASI score that followed each prior therapy trialled;
- the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- there is an absence of an adequate response to that treatment; or
- there was an intolerance to that treatment; or
- there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**



- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per

square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;
- (iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

1964J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

1963H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Enbrel [PF]

**■ ETANERCEPT**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

**(1) Initial treatment.**

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

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**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

- (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.



An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack

9037P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*846.11	31.60	Enbrel [PF]

#### ■ ETANERCEPT

##### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab,

tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater

than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
- (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:



(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be at least 18 years of age.

### Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9461Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

#### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9091L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	846.09	31.60	<sup>a</sup> Brenzys [RF]	<sup>a</sup> Enbrel [PF]

### ■ GOLIMUMAB

#### **Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

#### **golimumab 100 mg/mL injection, 1 mL pen device**

11502J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1124.06	31.60	Simponi [JC]

#### ■ GOLIMUMAB

##### **Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy

and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt. Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle. A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11521J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

11516D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

## ■ GOLIMUMAB

### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and

measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

**14604**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

#### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

13706J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

#### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

13699B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

### ■ GOLIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

##### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

##### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.



An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11373N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3432P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

### ■ GOLIMUMAB

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11375Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3428K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

**■ GOLIMUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:
  - (1) a completed authority prescription form; and
  - (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11376R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3436W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1161.96	31.60	Simponi [JC]

### **■ GOLIMUMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**golimumab 100 mg/mL injection, 1 mL pen device**

11381B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1124.06	31.60	Simponi [JC]

▪ **GOLIMUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.



An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

#### **Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**golimumab 100 mg/mL injection, 1 mL pen device**

11382C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3295.89	31.60	Simponi [JC]

**■ GOLIMUMAB****Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted

and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

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# **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

## **Clinical criteria:**

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- a CRP measurement no greater than 10 mg per L; or
- a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records:

- the BASDAI score; and
- the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

# **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks duration under this restriction.

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records:

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11538G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

#### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11560K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

### ■ GOLIMUMAB

#### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years)

[further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a



minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11365E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

#### **golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3430M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

### ■ GOLIMUMAB

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed,

(c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11372M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

**■ GOLIMUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID

therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be at least 18 years of age.

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online



Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11361Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

#### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3434R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.96	31.60	Simponi [JC]

### ■ INFLIXIMAB

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a

different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

12566J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	293.41	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

12555T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	384.18	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

### Authority required

Severe psoriatic arthritis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

### Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

### infliximab 120 mg/mL injection, 1 mL pen device

13056E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

### infliximab 120 mg/mL injection, 1 mL syringe

13078H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

### Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

### Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

### infliximab 120 mg/mL injection, 1 mL pen device

13070X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

### infliximab 120 mg/mL injection, 1 mL syringe

13058G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

- (1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
- (2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

#### Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

#### Population criteria:

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

### infliximab 120 mg/mL injection, 1 mL pen device

13061K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

### infliximab 120 mg/mL injection, 1 mL syringe

13074D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

- (1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
- (2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

13075E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

**infliximab 120 mg/mL injection, 1 mL syringe**

13065P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

**■ INFLIXIMAB****Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

**infliximab 120 mg/mL injection, 1 mL pen device**

12584H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

**infliximab 120 mg/mL injection, 1 mL syringe**

12550M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

■ **INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- the patient has never been prescribed the newly listed biological medicine; and
- the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

#### Population criteria:

- Patient must be at least 18 years of age.

#### infliximab 120 mg/mL injection, 1 mL pen device

12567K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

12597B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an



alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

12587L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

12552P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### **Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are

included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**infliximab 120 mg/mL injection, 1 mL pen device**

12554R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

**infliximab 120 mg/mL injection, 1 mL syringe**

12553Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

**■ INFLIXIMAB****Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

#### Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

#### infliximab 120 mg/mL injection, 1 mL pen device

12560C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

12586K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### Authority required

Severe Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### infliximab 120 mg/mL injection, 1 mL pen device

12551N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

12585J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:  
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.  
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### infliximab 120 mg/mL injection, 1 mL pen device

12575W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

12561D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### **Note** PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

- (1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed,



(c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
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**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### infliximab 120 mg/mL injection, 1 mL pen device

12577Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

12576X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### INFLIXIMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy

(Initial 1 - New patient); or,  
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,  
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).  
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).  
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

**infliximab 120 mg/mL injection, 1 mL pen device**

13054C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

**infliximab 120 mg/mL injection, 1 mL syringe**

13047Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

## ■ INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised

treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

**(3) Continuing treatment.**

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

**(4) Changing therapy.**

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

**(5) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

All measurements provided must be no more than 1 month old at the time of application.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

13048R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

13069W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:  
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.  
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### **Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

13049T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

13057F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### **■ INFLIXIMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious

infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

#### (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted



within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the condition is affecting the whole body, an adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. State the qualifying PASI score in the authority application.

Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) A reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or
- (ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle. State the qualifying numerical percentage figure in the authority application for each affected area.

All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

13076F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

**infliximab 120 mg/mL injection, 1 mL syringe**

13050W

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*759.91	31.60	Remsima SC [EW]

**■ INFLIXIMAB****Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### **Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

13055D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

13072B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### **■ INFLIXIMAB**

#### **Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the

alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy. A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

- (1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
- (2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The most recent fistula assessment must be no more than 1 month old at the time of application.

#### **infliximab 120 mg/mL injection, 1 mL pen device**

13060J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*578.35	31.60	Remsima SC [EW]

#### **infliximab 120 mg/mL injection, 1 mL syringe**

13073C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*759.91	31.60	Remsima SC [EW]

### **■ INFLIXIMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-

subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:  
(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.  
(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### infliximab 120 mg/mL injection, 1 mL pen device

13062L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

13067R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

### ■ INFLIXIMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab,

ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online



Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

- Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:
- (1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.
  - (2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

#### Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

- (i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;
- (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

#### infliximab 120 mg/mL injection, 1 mL pen device

13077G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*578.35	31.60	Remsima SC [EW]

#### infliximab 120 mg/mL injection, 1 mL syringe

13066Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*759.91	31.60	Remsima SC [EW]

#### Interleukin inhibitors

#### ■ BIMEKIZUMAB

##### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a

treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

#### (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

#### (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy

of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

13652M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3422.60	31.60	Bimzelx [UC]

#### **■ BIMEKIZUMAB**

##### **Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological

medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**

- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
  - (a) a CRP measurement no greater than 10 mg per L; or
  - (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2024, **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
  - (a) a CRP measurement no greater than 10 mg per L; or
  - (b) a CRP measurement reduced by at least 20% from baseline.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14589W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3422.60	31.60	Bimzelx [UC]

#### ■ BIMEKIZUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

- (iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Commencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and commencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- (iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Commencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

#### (2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

#### (3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

#### (4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

#### (5) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

#### (6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.



If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

14593C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3422.60	31.60	Bimzelx [UC]

▪ **BIMEKIZUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for

administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

14625R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3422.60	31.60	Bimzelx [UC]

**■ BIMEKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic

arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological

therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received treatment with this drug for this PBS indication prior to 1 October 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition if the patient has received non-PBS-subsidised treatment for at least 12 weeks, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (a) details of the proposed prescription; and,
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- (c) the date of commencement of this drug; and
- (d) results of the baseline patient assessment prior to initiation of non-PBS-subsidised therapy with this drug.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14590X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3422.60	31.60	Bimzelx [UC]

## ■ BIMEKIZUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot

change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.  
To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
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Reply Paid 9826  
HOBART TAS 7001

### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be at least 18 years of age.

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

14618J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3422.60	31.60	Bimzelx [UC]

**■ BIMEKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

**(1) Initial treatment.**

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

**(2) Grandfather patients (bimekizumab).**

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

**(3) Continuing treatment.**

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

**(4) Changing therapy.**

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

**(5) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2024, **AND**
- Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have demonstrated an adequate response after 16 weeks of treatment if the patient has been treated with this drug for this condition for 16 weeks or longer, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) baseline and current BASDAI scores; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)



**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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Reply Paid 9826

HOBART TAS 7001

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14602M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3422.60	31.60	Bimzelx [UC]

## ■ BIMEKIZUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate PBS-restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

## (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

## (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

## (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

## (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

## (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
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HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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HOBART TAS 7001

### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be at least 18 years of age.

## **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.
- Treatment criteria:**
- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

13644D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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## ■ GUSELKUMAB

### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.



However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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Or mailed to:

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#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **guselkumab 100 mg/mL injection, 1 x 1 mL pen device**

12568L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3615.49	31.60	Tremfya [JC]

#### **guselkumab 100 mg/mL injection, 1 x 1 mL syringe**

12590P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3615.49	31.60	Tremfya [JC]

### **■ GUSELKUMAB**

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-

subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

#### Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

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HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:



(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

## **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

## **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
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Complex Drugs  
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HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**guselkumab 100 mg/mL injection, 1 x 1 mL syringe**

11614G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3615.49	31.60	Tremfya [JC]

**IXEKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

12209N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3259.60	31.60	Taltz [LY]

**■ IXEKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.



A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

11033Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3259.60	31.60	Taltz [LY]

**■ IXEKIZUMAB****Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

**(1) Initial treatment.**

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

**(2) Grandfather patients (bimekizumab).**

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

**(3) Continuing treatment.**

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

**(4) Changing therapy.**

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

**(5) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12217B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3259.60	31.60	Taltz [LY]

## IXEKIZUMAB

### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior to the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**



Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11623R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3259.60	31.60	Taltz [LY]

## ■ IXEKIZUMAB

### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

### Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be aged 18 years or older.

### Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**



- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

11032P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	3259.60	31.60	Taltz [LY]

**■ RISANKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

## **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be at least 18 years of age.

## **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
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HOBART TAS 7001

## **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**risankizumab 150 mg/mL injection, 1 mL pen device**

14142H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	5139.93	31.60	Skyrizi [VE]

▪ **RISANKIZUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed

treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**



- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**risankizumab 150 mg/mL injection, 1 mL pen device**

14732J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5139.93	31.60	Skyrizi [VE]

**■ RISANKIZUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte

sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2025, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition if the patient has received non-PBS-subsidised treatment for at least 12 weeks, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  
either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  
either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- details of the proposed prescription; and,
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- the date of commencement of this drug; and
- results of the baseline patient assessment prior to initiation of non-PBS-subsidised therapy with this drug.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### risankizumab 150 mg/mL injection, 1 mL pen device

14713J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	5139.93	31.60	Skyrizi [VE]

## ■ RISANKIZUMAB

### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before

they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of

disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:



(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

### Population criteria:

- Patient must be at least 18 years of age.

### Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a dermatologist.
- The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

#### Treatment criteria:

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### risankizumab 150 mg/mL injection, 1 mL pen device

14111Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5139.93	31.60	Skyrizi [VE]

#### SECUKINUMAB

##### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

##### Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break

in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

#### secukinumab 150 mg/mL injection, 1 mL pen device

10893H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	711.03	31.60	Cosentyx [NV]

#### ■ SECUKINUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

#### Treatment criteria:

- Must be treated by a dermatologist.

#### secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14164L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1405.07	31.60	Cosentyx [NV]

### ■ SECUKINUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10494H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1405.07	31.60	Cosentyx [NV]

**■ SECUKINUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10901R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1405.07	31.60	Cosentyx [NV]

#### secukinumab 150 mg/mL injection, 1 mL pen device

10898N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	711.03	31.60	Cosentyx [NV]

### ■ SECUKINUMAB

#### **Note** TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological



medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **secukinumab 150 mg/mL injection, 1 mL pen device**

10906B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	711.03	31.60	Cosentyx [NV]

## **■ SECUKINUMAB**

### **Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**secukinumab 150 mg/mL injection, 1 mL pen device**

12297F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	711.03	31.60	Cosentyx [NV]

**■ SECUKINUMAB****Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the

C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
  - (a) a CRP measurement no greater than 10 mg per L; or
  - (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

#### **secukinumab 150 mg/mL injection, 1 mL pen device**

12307R	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	711.03	31.60	Cosentyx [NV]

### ▪ SECUKINUMAB

#### **Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe

hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 16 weeks of treatment if the patient has been treated with this drug for this condition for 16 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription; and
- (b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count; and
  - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
  - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
  - (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 16 weeks or more of treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

14146M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1405.07	31.60	Cosentyx [NV]

**■ SECUKINUMAB****Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and



- (ii) the AN count; and
- (iii) the name of the antibiotic/s received for two separate courses each of three months; or
- (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

#### secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14161H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1405.07	31.60	Cosentyx [NV]

### ■ SECUKINUMAB

#### Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

- (1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

- (2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

- (3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

- (4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

- (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

- (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

This restriction is intended for induction dosing only.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

#### **Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the Hurley stage grading; and
  - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

#### **secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

14154Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*5428.87	31.60	Cosentyx [NV]

#### **■ SECUKINUMAB**

##### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

## **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10899P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1405.07	31.60	Cosentyx [NV]

**secukinumab 150 mg/mL injection, 1 mL pen device**

10895K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	711.03	31.60	Cosentyx [NV]

**■ SECUKINUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

### **Authority required**



### Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### Authority required

### Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**secukinumab 150 mg/mL injection, 1 mL pen device**

10890E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2784.91	31.60	Cosentyx [NV]

**■ SECUKINUMAB****Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than

5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### secukinumab 150 mg/mL injection, 1 mL pen device

12321L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*3454.02	31.60	Cosentyx [NV]

### ■ SECUKINUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their

first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

#### (1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

#### (3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

#### (4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10425Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1405.07	31.60	Cosentyx [NV]



## ■ SECUKINUMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active

joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.  
(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.  
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR

- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10894J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*5428.87	31.60	Cosentyx [NV]

**secukinumab 150 mg/mL injection, 1 mL pen device**

10900Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2784.91	31.60	Cosentyx [NV]

**■ SECUKINUMAB****Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater

than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.



Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10910F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*5428.87	31.60	Cosentyx [NV]

**■ TILDRAKIZUMAB****Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **tildrakizumab 100 mg/mL injection, 1 mL syringe**

11613F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3117.15	31.60	Ilumya [RA]

### ■ TILDRAKIZUMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus

psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**



- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tildrakizumab 100 mg/mL injection, 1 mL syringe**

11616J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3117.15	31.60	Ilumya [RA]

**■ TOCILIZUMAB****Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break

in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

##### **14150**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11720W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11742B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra ACTPen [RO]

**■ TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept. Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12762Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12761P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra ACTPen [RO]

### ■ TOCILIZUMAB

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, AND
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab.

#### **Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12768B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12767Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra ACTPen [RO]

### ■ TOCILIZUMAB

#### Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.



Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14104**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be under 30kg, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

13301C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

13306H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra ACTPen [RO]

### ■ TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Active giant cell arteritis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11721X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11722Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	813.27	31.60	Actemra ACTPen [RO]

### ■ TOCILIZUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11730J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11750K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra ACTPen [RO]

## ■ TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### **Authority required**

Active giant cell arteritis

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

### **Clinical criteria:**

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; OR
- Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

### **Population criteria:**

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include:

(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and

(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11743C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11744D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra ACTPen [RO]

## ■ TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

### **Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe

active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

#### Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12102Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12094M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	813.27	31.60	Actemra ACTPen [RO]

## ■ TOCILIZUMAB

### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

13685G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

13720D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra ACTPen [RO]

### **■ TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:



From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**14088**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The following reports must be documented in the patient's medical records where appropriate:

(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and

(b) baseline and current pathology reports detailing platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12099T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12084B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra ACTPen [RO]

### ■ **TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented

in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**14084**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12086D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12090H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	813.27	31.60	Actemra ACTPen [RO]

▪ **TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, AND

- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, AND

- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12806B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12792G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra ACTPen [RO]

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### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10954M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11567T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	813.27	31.60	Actemra ACTPen [RO]

▪ **TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

### (5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.



The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11741Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11725D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra ACTPen [RO]

### **■ TOCILIZUMAB**

#### **Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii)

oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

#### Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11748H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11734N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra ACTPen [RO]

**■ TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis;
- (b) details of prior treatment including dose and duration of treatment; and
- (c) the pathology reports detailing CRP and platelet count where appropriate.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

- (a) in a patient with polyarticular course disease:



- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- (b) in a patient with refractory systemic symptoms:
  - (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
  - (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
  - (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12095N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12083Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra ACTPen [RO]

**■ TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

- (a) in a patient with polyarticular course disease:
  - (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retri or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12105D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12085C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	813.27	31.60	Actemra ACTPen [RO]

**■ TOCILIZUMAB**
**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).



To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10951J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra Subcutaneous Injection [RO]

#### **tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11565Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	813.27	31.60	Actemra ACTPen [RO]

### **■ USTEKINUMAB**

#### **Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a

treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment (Whole body, or, face/hand/foot)

#### Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed.

#### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12662K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3944.61	31.60	Stelara [JC]

### ■ USTEKINUMAB

#### **Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological

medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
  - Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].
- The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
  - (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- An adequate response is defined as:
- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
  - (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.
- The most recent fistula assessment must be no more than 1 month old at the time of application.
- At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

#### ustekinumab 90 mg/mL injection, 1 mL syringe

13789R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	2977.51	31.60	Stelara [JC]

### ■ USTEKINUMAB

#### Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

- (i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or
- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

- (i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

- (i) all subscores are rated moderate to severe; or

- (ii) 2 of the three subscores are rated severe to very severe; or
- (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Whole body) - treatment covering week 28 and onwards

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

12664M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3944.61	31.60	Stelara [JC]

▪ **USTEKINUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.



If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### ustekinumab 90 mg/mL injection, 1 mL syringe

13261Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	2977.51	31.60	Stelara [JC]

### ■ USTEKINUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy

(Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years)

[further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10767Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3944.61	31.60	Stelara [JC]

### ■ USTEKINUMAB

#### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

#### **Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9305R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3944.61	31.60	Stelara [JC]

#### **▪ USTEKINUMAB**

##### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].



**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**ustekinumab 90 mg/mL injection, 1 mL syringe**

13273N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2977.51	31.60	Stelara [JC]

**■ USTEKINUMAB**
**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle

and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or  
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or  
(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

## Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

## Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## ustekinumab 90 mg/mL injection, 1 mL syringe

13805N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2977.51	31.60	Stelara [JC]

## ■ USTEKINUMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy

(Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

## (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

## (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

## (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10774C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3944.61	31.60	Stelara [JC]

### ■ USTEKINUMAB

#### Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or



- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

- (i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

- (i) all subscores are rated moderate to severe; or
- (ii) 2 of the three subscores are rated severe to very severe; or
- (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Ustekinumab only:

To avoid an interruption of supply for continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except

etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** The 28-weeks of treatment provided by this listing is intended to cover doses occurring at week 0, week 4 and week 16. Based on body weight, request an amount of biological medicine sufficient to cover a dose occurring at these timepoints. The original prescription is intended to cover a dose at week 0 and the 2 repeat prescriptions available are intended to cover doses at week 4 and week 16.

The dose due at week 28 is obtained with the first prescription obtained under the 'Continuing treatment' phase. Remind the patient to return for clinical review at approximately week 24 of treatment to enable ample time to obtain the authority application enabling dosing from week 28 and onwards.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

- (i) the patient's response to treatment can be quantified; and
- (ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naïve patient

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) the PASI score that followed each prior therapy trialled;
- (iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or
- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

- (i) an absence of an adequate response; or
- (ii) an intolerance to that treatment; or
- (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 3 doses available under any of the initial treatment phases.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

- (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or
- (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;
- (iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

- (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);
- (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years

#### **Treatment criteria:**

- Must be treated by a dermatologist.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or
- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

- (i) an absence of an adequate response; or
- (ii) an intolerance to that treatment; or
- (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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HOBART TAS 7001

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12669T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3944.61	31.60	Stelara [JC]

## ■ USTEKINUMAB

### **Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is

increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of clinical assessment; and
  - (iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.



Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

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#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

#### **AND**

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
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HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
  - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

## ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

11178H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*7780.77	31.60	Stelara [JC]

**■ USTEKINUMAB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be aged 18 years or older.

#### Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs



Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9304Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3944.61	31.60	Stelara [JC]

General

*Calcineurin inhibitors*

■ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**ciclosporin 100 mg/mL oral liquid, 50 mL**

8661W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*700.05	31.60	Neoral [NV]

**ciclosporin 25 mg capsule, 30**

8658Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*60.87	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 25 [NV]

**ciclosporin 50 mg capsule, 30**

8659R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*112.11	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 50 [NV]

**ciclosporin 10 mg capsule, 60**

8657P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*93.47	31.60	Neoral 10 [NV]

**ciclosporin 100 mg capsule, 30**

8660T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*219.47	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 100 [NV]

■ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ciclosporin 100 mg/mL oral liquid, 50 mL**

14001X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*1391.63	31.60	Neoral [NV]

**ciclosporin 25 mg capsule, 30**

13883Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*108.27	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 25 [NV]

**ciclosporin 50 mg capsule, 30**

13910D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*215.59	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 50 [NV]

**ciclosporin 10 mg capsule, 60**

13999T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*176.47	31.60	Neoral 10 [NV]

**ciclosporin 100 mg capsule, 30**

13911E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*430.47	31.60	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 100 [NV]

■ **TACROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**tacrolimus 500 microgram capsule, 100**

8646C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	68.81	31.60	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> Tacrograf [RW]

<sup>a</sup> Tacrolimus Sandoz [SZ]**tacrolimus 500 microgram modified release capsule, 30**

5299X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	53.80	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg capsule, 100**

8647D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	124.70	31.60	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 3 mg modified release capsule, 50**

11914C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	380.00	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg modified release capsule, 60**

5300Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	79.89	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 5 mg capsule, 50**

8648E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	298.92	31.60	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> Tacrograf [RW]	<sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]

**tacrolimus 5 mg modified release capsule, 30**

5451X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	430.86	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 750 microgram capsule, 100**

10870D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	119.19	31.60	Tacrolimus Sandoz [SZ]	

**tacrolimus 2 mg capsule, 100**

10871E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	273.38	31.60	Tacrolimus Sandoz [SZ]	

**■ TACROLIMUS****Caution** Careful monitoring of patients is mandatory.**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**tacrolimus 500 microgram capsule, 100**

13908B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*124.69	31.60	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 500 microgram modified release capsule, 30**

13907Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*94.15	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg capsule, 100**

14070M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*240.93	31.60	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 3 mg modified release capsule, 50**

13996P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*751.55	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg modified release capsule, 60**

13962W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*147.97	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 5 mg capsule, 50**

13909C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*589.39	31.60	<sup>a</sup> Pharmacor Tacrolimus 5 [CR]	<sup>a</sup> Prograf [LL]

<sup>a</sup> Tacrograf [RW]

<sup>a</sup> Tacrolimus Sandoz [SZ]

**tacrolimus 5 mg modified release capsule, 30**

14039X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*853.27	31.60	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 750 microgram capsule, 100**

14066H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*229.93	31.60	Tacrolimus Sandoz [SZ]

**tacrolimus 2 mg capsule, 100**

13995N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*538.29	31.60	Tacrolimus Sandoz [SZ]

*Sphingosine-1-phosphate (S1P) receptor modulators*

■ **ETRASIMOD**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
  - Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
  - Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].
- Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation, **AND**
- The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR
- The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR
- Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment; and
  - (ii) the date of commencement of this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **etrasimod 2 mg tablet, 28**

14601L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1434.07	31.60	Velsipity [PF]

### ■ ETRASIMOD

#### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

## **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

## **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

## **Clinical criteria:**



- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **etrasimod 2 mg tablet, 28**

14600K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1434.07	31.60	Velsipity [PF]

#### **■ FINGOLIMOD**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required (STREAMLINED)**

**16325**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

#### **Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

#### **Population criteria:**

- Patient must weigh 40 kg or less.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

#### **Authority required (STREAMLINED)**

**16346**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Population criteria:**

- Patient must weigh 40 kg or less.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

 **fingolimod 250 microgram capsule, 28**

11818B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1063.91	31.60	Gilenya [NV]

**■ FINGOLIMOD**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)****16301**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

 **fingolimod 500 microgram capsule, 28**

5262Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	936.59	31.60	<sup>a</sup> AKM Fingolimod [RW] <sup>a</sup> Fingolimod Sandoz [SZ] <sup>a</sup> Fingolimod-Teva [TB] <sup>a</sup> Gilenya [NV]	<sup>a</sup> Fingolimod Dr.Reddy's [RZ] <sup>a</sup> Fingolimod SUN [RA] <sup>a</sup> Fynod [AF] <sup>a</sup> Pharmacor Fingolimod [CR]

**■ OZANIMOD**

**Note** Ensure that PBS-subsidy is approved for the 920 mcg strength prior to supply of this titration pack. It is advisable to only have the titration pack prescription dispensed at the same time as a prescription for the 920 mcg capsules, or where a supply of the 920 mcg capsules is already in existence (in the case of mid treatment dose interruption).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****14017**

Moderate to severe ulcerative colitis

Treatment Phase: Dose escalation occurring at initial treatment or re-initiation of treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7**

13251K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	589.39	31.60	Zeposia [BQ]

▪ **OZANIMOD**

**Note** The initiation pack is intended for use at the commencement of treatment and for re-initiation of therapy following treatment interruption. The first prescription for the 920 microgram capsules should occur under the Initial treatment restriction. Subsequent prescriptions should then occur under the Continuing treatment restriction. If treatment interruption of more than 14 consecutive days occurs for reasons other than lack of efficacy, apply under the Continuing treatment restriction for each of the Initiation pack and 920 microgram capsules. If treatment interruption occurs within the first 14 days, or, for more than 7 consecutive doses between treatment Days 15 to 28, re-apply for an initiation pack under the 'Initial treatment' treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**16301**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**ozanimod 920 microgram capsule, 28**

12271W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	2220.89	31.60	Zeposia [BQ]

**ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7**

12278F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	589.39	31.60	Zeposia [BQ]

▪ **OZANIMOD**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**ozanimod 920 microgram capsule, 28**

13269J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2220.89	31.60	Zeposia [BQ]

**■ OZANIMOD**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**

- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

- (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.
- An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs



Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ozanimod 920 microgram capsule, 28**

13271L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2220.89	31.60	Zeposia [BQ]

▪ **SIPONIMOD**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16347**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have mild disability in at least 3 functional systems; OR
- Patient must have moderate disability in at least 1 functional system.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.

**Note** There is no specific Medical Benefits Schedule item for CYP2C9 metabolising enzyme status testing.

**Authority required (STREAMLINED)**

**16303**

Multiple sclerosis

Treatment Phase: Continuing treatment (including recommencement of treatment)

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**siponimod 250 microgram tablet, 12**

12172P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	240.84	31.60	Mayzent [NV]

**siponimod 250 microgram tablet, 120**

12160B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	2220.90	31.60	Mayzent [NV]

**siponimod 2 mg tablet, 28**

12158X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	2220.89	31.60	Mayzent [NV]

**siponimod 1 mg tablet, 28**

14607T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	2082.44	31.60	Mayzent [NV]

**Janus-associated kinase (JAK) inhibitors****■ BARICITINIB****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
 (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**baricitinib 2 mg tablet, 28**

13689L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1046.01	31.60	Olumiant [LY]

**baricitinib 4 mg tablet, 28**

13702E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1046.01	31.60	Olumiant [LY]

**■ BARICITINIB****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a

written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**baricitinib 2 mg tablet, 28**

11442F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1046.01	31.60	Olumiant [LY]

**baricitinib 4 mg tablet, 28**

11443G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1046.01	31.60	Olumiant [LY]

**■ BARICITINIB****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction

necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot

be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**



- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**baricitinib 2 mg tablet, 28**

11437Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1046.01	31.60	Olumiant [LY]

**baricitinib 4 mg tablet, 28**

11447L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1046.01	31.60	Olumiant [LY]

▪ **DEUCRAVACITINIB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**15406**

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

**Population criteria:**

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to deucravacitinib, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**deucravacitinib 6 mg tablet, 28**

13649J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1259.99	31.60	Sotyktu [BQ]

▪ **TOFACITINIB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in

their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**14697**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### tofacitinib 1 mg/mL oral liquid, 240 mL

13738C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	1212.40	31.60	Xeljanz [PF]

### ■ TOFACITINIB

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or  
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tofacitinib 5 mg tablet, 56**

13730P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

**■ TOFACITINIB**
**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**14697**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### tofacitinib 5 mg tablet, 56

13737B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

### ■ TOFACITINIB

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1



application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

10511F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

**TOFACITINIB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

#### (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

11675L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

**■ TOFACITINIB**
**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

13345J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

**▪ TOFACITINIB****Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

#### Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under the Balance of supply restriction to complete up to 24 weeks continuing treatment.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under this restriction to complete up to 24 weeks continuing treatment.

**tofacitinib 5 mg tablet, 56**

12557X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1212.40	31.60	Xeljanz [PF]

**tofacitinib 10 mg tablet, 56**

12589N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1980.95	31.60	Xeljanz [PF]

**■ TOFACITINIB****Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or



continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

#### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### tofacitinib 1 mg/mL oral liquid, 240 mL

13770R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	1212.40	31.60	Xeljanz [PF]

### ▪ TOFACITINIB

#### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD

treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated

according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### tofacitinib 5 mg tablet, 56

10517M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1212.40	31.60	Xeljanz [PF]

## ■ TOFACITINIB

### **Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.



(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

## **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

11690G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1212.40	31.60	Xeljanz [PF]

**■ TOFACITINIB**
**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR

- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

#### **Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

12556W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1212.40	31.60	Xeljanz [PF]

**tofacitinib 10 mg tablet, 56**

12588M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1980.95	31.60	Xeljanz [PF]

■ **TOFACITINIB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as

initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:



- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **tofacitinib 5 mg tablet, 56**

13755Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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### **■ TOFACITINIB**

#### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **tofacitinib 5 mg tablet, 56**

13349N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1212.40	31.60	Xeljanz [PF]

### **■ UPADACITINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands

#### **Treatment criteria:**

- Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions, **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true: (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled', **AND**
- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

### **upadacitinib 15 mg modified release tablet, 28**

12835M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.78	31.60	Rinvoq [VE]

**upadacitinib 30 mg modified release tablet, 28**

12827D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2077.76	31.60	Rinvoq [VE]

**■ UPADACITINIB**

**Note** The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe Crohn disease

Treatment Phase: Extended induction period (optional) from weeks 12 to 24

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have experienced an inadequate therapeutic benefit following at least one of: (i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily.

**Population criteria:**

- Patient must be at least 18 years of age.

**upadacitinib 30 mg modified release tablet, 28**

13762H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2077.76	31.60	Rinvoq [VE]

**■ UPADACITINIB****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'.

Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required (STREAMLINED)**

**14499**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:



(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
 (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:  
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
 The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

#### upadacitinib 15 mg modified release tablet, 28

14125K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

#### ■ UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any further authority applications occurring immediately after access through this dose modification listing are not to occur through any of the following Treatment phase listings: (i) Balance of Supply, (ii) Initial Treatment.

#### **Note Dose modification**

Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Dose modification

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy.

#### upadacitinib 15 mg modified release tablet, 28

13256Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1272.78	31.60	Rinvoq [VE]

#### upadacitinib 30 mg modified release tablet, 28

13265E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	2077.76	31.60	Rinvoq [VE]

#### ■ UPADACITINIB

#### **Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a

minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
  - (a) a CRP measurement no greater than 10 mg per L; or
  - (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**upadacitinib 15 mg modified release tablet, 28**

13343G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

**■ UPADACITINIB****Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

**Continuing subsidy:**

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

**Balance of Supply listings:**

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**(2) Baseline measurements to determine response.**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **upadacitinib 15 mg modified release tablet, 28**

11979L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

#### **■ UPADACITINIB**

##### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

## (1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

## (2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

## (3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

## (4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

## (5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

## (6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

12621G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

## ■ UPADACITINIB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in

biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).



The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **upadacitinib 15 mg modified release tablet, 28**

12648Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

#### **■ UPADACITINIB**

##### **Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

- (1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose strength change is required, see 'Dose modification' treatment phase to continue treatment at a new dose strength.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance of 24 weeks treatment.

#### **upadacitinib 15 mg modified release tablet, 28**

13250J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

**upadacitinib 30 mg modified release tablet, 28**

13249H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2077.76	31.60	Rinvoq [VE]

**■ UPADACITINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:

<https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**

- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

- (i) erythema,
- (ii) oedema/papulation,
- (iii) excoriation,
- (iv) lichenification

Acceptable scores can be:

- (a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**upadacitinib 15 mg modified release tablet, 28**

12828E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1272.78	31.60	Rinvoq [VE]

**upadacitinib 30 mg modified release tablet, 28**

12836N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	2077.76	31.60	Rinvoq [VE]

**■ UPADACITINIB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:

<https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR

- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority required**

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

**upadacitinib 15 mg modified release tablet, 28**

12831H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

**upadacitinib 30 mg modified release tablet, 28**

12829F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2077.76	31.60	Rinvoq [VE]

**■ UPADACITINIB****Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

Treatment cycles:

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted. Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt. Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or

(iii) a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

(iv) a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Changing the prescribed biological medicine.

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

(6) Balance of Supply

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR



- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

13350P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.78	31.60	Rinvoq [VE]

**■ UPADACITINIB**
**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- the patient has never been prescribed the newly listed biological medicine; and
- the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR
- The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose:

- (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or
- (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for the Continuing (maintenance) treatment phase

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Continuing (maintenance) treatment aims to provide 24 weeks.

### **upadacitinib 30 mg modified release tablet, 28**

13746L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2077.76	31.60	Rinvoq [VE]

## ■ UPADACITINIB

### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

#### Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose:

- (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or
- (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for the Continuing (maintenance) treatment phase

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Continuing (maintenance) treatment aims to provide 24 weeks.

### upadacitinib 15 mg modified release tablet, 28

13768P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1272.78	31.60	Rinvoq [VE]

## ■ UPADACITINIB

### Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in

biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
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Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply



**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

11989B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.78	31.60	Rinvoq [VE]

**■ UPADACITINIB**
**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years)

[further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.  
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
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Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### upadacitinib 15 mg modified release tablet, 28

12624K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.78	31.60	Rinvoq [VE]

### ■ UPADACITINIB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient - untreated with biological medicine)

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
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HOBART TAS 7001

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

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#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **upadacitinib 45 mg modified release tablet, 28**

13262B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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### ■ UPADACITINIB

#### **Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.



Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be at least 18 years of age.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
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#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
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#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

12625L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.78	31.60	Rinvoq [VE]

## UPADACITINIB

### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

(i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and

(ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting

the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** The prescriber completing this authority application must be a specialist medical practitioner of the type specified in the restriction.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Severe Crohn disease

Treatment Phase: Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine)

### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### Population criteria:

- Patient must be at least 18 years of age.

### Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion

must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The treatment must not have on a previous occasion failed to provide the patient with an adequate response during the current treatment cycle.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In relation to the biological medicine prescribed immediately before this one, provide at least one of the following which is not more than 4 weeks from the last administered dose:

- (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or
- (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; or
- (iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Provide at least one of the following:

- (i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on;
- (ii) confirmation that there is a documented history of intestinal inflammation plus diagnostic imaging/surgical evidence of at least one of: (a) short gut syndrome, (b) ileostomy, (c) colostomy;
- (iii) confirmation that there is a documented history and radiological evidence of intestinal inflammation from extensive small intestinal disease affecting more than 50 cm of the small intestine where the CDAI score is at least 220, but below 300.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for Initial (induction) treatment phases

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Initial (induction) treatment phases and 'Extended induction' treatment phases for this benefit aim to provide 12 weeks treatment duration.

**upadacitinib 45 mg modified release tablet, 28**

13771T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2717.45	31.60	Rinvoq [VE]

**Monoclonal antibodies**

▪ **OFATUMUMAB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16301**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

12641H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	2184.80	31.60	Kesimpta [NV]

**■ OFATUMUMAB**

**Note** The intent of this listing is to provide doses at weeks 0, 1 and 2. For treatment at week 4 and beyond, see the 'Continuing treatment' listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

12642J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	..	..	*6337.47	31.60	Kesimpta [NV]

**■ VEDOLIZUMAB****Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- the patient has never been prescribed the newly listed biological medicine; and
- the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment



discontinuation will be exempted from being counted as an inadequate response.  
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.  
Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12620F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1747.77	31.60	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and

(iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment with subcutaneous form

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Where four initial doses of vedolizumab (at weeks 0, 2, 6 and 10) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (4 weeks after the fourth dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

#### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12638E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1747.77	31.60	Entyvio [TK]

### ▪ VEDOLIZUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); OR
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); OR
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

**Population criteria:**

- Patient must be at least 18 years of age.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

- (a) details of the proposed prescription(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12644L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1747.77	31.60	Entyvio [TK]

**■ VEDOLIZUMAB****Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply - subcutaneous form

#### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

#### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12647P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1747.77	31.60	Entyvio [TK]

### VEDOLIZUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

### (3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

### (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

### (5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

### **Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### **vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12639F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1747.77	31.60	Entyvio [TK]

## ▪ VEDOLIZUMAB

### **Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current

treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

**Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12654B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1747.77	31.60	Entyvio [TK]

**Mammalian target of rapamycin (mTOR) kinase inhibitors****■ EVEROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**everolimus 250 microgram tablet, 60**

8840G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	179.99	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

**everolimus 500 microgram tablet, 60**

8841H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	307.87	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

**everolimus 750 microgram tablet, 60**

8842J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*872.29	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

**everolimus 1 mg tablet, 60**

9352F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*1150.77	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

**■ EVEROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**



The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**everolimus 750 microgram tablet, 60**

14040Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*1736.15	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

**everolimus 1 mg tablet, 60**

13941R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*2284.31	31.60	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

▪ **SIROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**sirolimus 1 mg/mL oral liquid, 60 mL**

8725F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	521.99	31.60	Rapamune [PF]

**sirolimus 500 microgram tablet, 100**

8984W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	340.11	31.60	Rapamune [PF]

**sirolimus 1 mg tablet, 100**

8724E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	653.78	31.60	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

8833X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1270.70	31.60	Rapamune [PF]

▪ **SIROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sirolimus 1 mg/mL oral liquid, 60 mL**

13885T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	3	..	*1035.53	31.60	Rapamune [PF]

**sirolimus 500 microgram tablet, 100**

13860L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*671.77	31.60	Rapamune [PF]

**sirolimus 1 mg tablet, 100**

14072P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1299.09	31.60	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

13886W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*2512.73	31.60	Rapamune [PF]

*Complement inhibitors*

▪ **AVACOPAN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be severe granulomatosis with polyangiitis; OR
- The condition must be severe microscopic polyangiitis, **AND**
- The condition must be active at the time of the first prescription for this drug per treatment cycle, **AND**
- Patient must have ANCA associated vasculitis that is either: (i) organ-threatening, (ii) life-threatening disease, **AND**

- Patient must be undergoing concomitant therapy with at least another drug therapy as part of a regimen specified in this drug's approved Product Information, **AND**
  - Patient must not receive more than 12 months of PBS-subsidised treatment with this drug per induction.
- A prescriber may apply for more than one induction treatment for their patient

**avacopan 10 mg capsule, 180**

14605Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8485.80	31.60	Tavneos [CS]

*Dihydroorotate dehydrogenase (DHODH) inhibitors***LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

5449T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	26.23	27.68	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]

**leflunomide 20 mg tablet, 30**

5450W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	32.91	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]

**LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

8374R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	26.23	27.68	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]

**leflunomide 20 mg tablet, 30**

8375T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	32.91	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ] <sup>a</sup> Lunava 20 [RW]

**LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active rheumatoid arthritis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

13940Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*39.01	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ] <sup>a</sup> Lunava 10 [RW]

**leflunomide 20 mg tablet, 30**

14069L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*52.37	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ] <sup>a</sup> Lunava 20 [RW]

**LEFLUNOMIDE**

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

Severe active psoriatic arthritis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

14068K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*39.01	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 10 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]

**leflunomide 20 mg tablet, 30**

13998R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*52.37	31.60	<sup>a</sup> APO-LEFLUNOMIDE [TX] <sup>a</sup> Ataris 20 [AF] <sup>a</sup> Leflunomide generichealth [HQ] <sup>a</sup> LEFLUNOMIDE-WGR [WG]	<sup>a</sup> Arava [SW] <sup>a</sup> Leflunomide APOTEX [GX] <sup>a</sup> Leflunomide Sandoz [SZ]

**TERIFLUNOMIDE**

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)****16315**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**teriflunomide 14 mg tablet, 28**

2898M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	117.41	31.60	<sup>a</sup> APO-TERIFLUNOMIDE [TX] <sup>a</sup> TERIFLAGIO [RW] <sup>a</sup> Teriflunomide GH [GQ] <sup>a</sup> Terimide [AF]	<sup>a</sup> Pharmacor Teriflunomide [CR] <sup>a</sup> Teriflunomide Dr.Reddy's [RZ] <sup>a</sup> Teriflunomide Sandoz [SZ]

*Other immunosuppressants***■ AZATHIOPRINE****azathioprine 25 mg tablet, 100**

2688L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.85	23.30	<sup>a</sup> APO-Azathioprine [TX] <sup>a</sup> AZATHIOPRINE-WGR [WG]	<sup>a</sup> Azathioprine Sandoz [SZ] <sup>a</sup> NOUMED AZATHIOPRINE [VO]
			<sup>b</sup> 6.00	27.85	23.30	<sup>a</sup> Imuran [AS]	

**azathioprine 50 mg tablet, 100**

2687K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.75	29.20	<sup>a</sup> APO-Azathioprine [TX] <sup>a</sup> Azathioprine Sandoz [SZ] <sup>a</sup> Imazan [ZS]	<sup>a</sup> Azapin [RW] <sup>a</sup> AZATHIOPRINE-WGR [WG] <sup>a</sup> NOUMED AZATHIOPRINE [VO]
			<sup>b</sup> 6.00	33.75	29.20	<sup>a</sup> Thioprine 50 [AF] <sup>a</sup> Imuran [AS]	

**■ DIMETHYL FUMARATE****Authority required (STREAMLINED)****16315**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2943X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*267.27	31.60	<sup>a</sup> APO-DIMETHYL FUMARATE [XT] <sup>a</sup> Pharmacor Dimethyl Fumarate [CR]	<sup>a</sup> Dimethyl Fumarate Sandoz [SZ] <sup>a</sup> Tecfidera [BD]

**dimethyl fumarate 240 mg enteric capsule, 56**

2966D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	451.93	31.60	<sup>a</sup> APO-DIMETHYL FUMARATE [XT] <sup>a</sup> Pharmacor Dimethyl Fumarate [CR] <sup>a</sup> Trazent [AF]	<sup>a</sup> Dimethyl Fumarate Sandoz [SZ] <sup>a</sup> Tecfidera [BD]

▪ **DIMETHYL FUMARATE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

2896K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*267.27	31.60	<sup>a</sup> APO-DIMETHYL FUMARATE [XT] <sup>a</sup> Pharmacor Dimethyl Fumarate [CR]	<sup>a</sup> Dimethyl Fumarate Sandoz [SZ] <sup>a</sup> Tecfidera [BD]

▪ **DIROXIMEL FUMARATE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**16323**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**16315**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; OR
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**diroxime fumarate 231 mg enteric capsule, 120**

13059H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	715.73	31.60	Vumerity [BD]

**■ METHOTREXATE****methotrexate 10 mg tablet, 15**

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	25.56	27.01	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

**methotrexate 2.5 mg tablet, 30**

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.29	20.74	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

**methotrexate 10 mg tablet, 10**

14643Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.52	22.97	<sup>a</sup> Chexate [OX]	<sup>a</sup> Methoblastin [PF]

**■ METHOTREXATE****Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	53.78	31.60	<sup>a</sup> ARX-Methotrexate [XT] <sup>a</sup> Methoblastin [PF]	<sup>a</sup> Chexate [OX]

**■ METHOTREXATE****Authority required (STREAMLINED)****7488**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**Authority required (STREAMLINED)****7518**

Severe psoriasis

**Clinical criteria:**

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe**

11268C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe**

11288D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe**

11295L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe**

11275K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe**

11283W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.87	31.60	Trexject [LM]

▪ **METHOTREXATE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**15068**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe**

14102F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe**

14097Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe**

14103G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe**

14091P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*90.87	31.60	Trexject [LM]

**methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe**

14089M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*90.87	31.60	Trexject [LM]

▪ **PIRFENIDONE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**pirfenidone 801 mg tablet, 90**

11410M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	517.40	31.60	<sup>a</sup> ARX-Pirfenidone [XW] <sup>a</sup> Pirfenidone Ameda [XT] <sup>a</sup> Pirfenidone Sandoz [SZ]	<sup>a</sup> Pirfenidet [AF] <sup>a</sup> Pirfenidone Dr.Reddy's [RZ]

▪ **PIRFENIDONE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment



**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**pirfenidone 267 mg tablet, 90**

11406H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*517.38	31.60	<sup>a</sup> ARX-Pirfenidone [XW] <sup>a</sup> Pirfenidone Ameda [XT] <sup>a</sup> Pirfenidone Sandoz [SZ]	<sup>a</sup> Pirfenidet [AF] <sup>a</sup> Pirfenidone Dr.Reddy's [RZ]

**■ MUSCULO-SKELETAL SYSTEM****■ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS****ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS***Acetic acid derivatives and related substances***■ DICLOFENAC****diclofenac sodium 100 mg suppository, 20**

1302M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	3	..	*29.89	31.34	Voltaren 100 [NV]

**diclofenac sodium 100 mg suppository, 20**

5079H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*29.89	31.34	Voltaren 100 [NV]

**diclofenac sodium 25 mg enteric tablet, 50**

1299J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	2	3	..	*18.89	20.34	<sup>a</sup> Clonac 25 [RW] <sup>a</sup> DICLOFENAC-WGR [WG]	<sup>a</sup> Diclofenac Sandoz [SZ] <sup>a</sup> Fenac EC [AL]
			<sup>B</sup> 4.96	*23.85	20.34	<sup>a</sup> Voltaren 25 [NV]	

**diclofenac sodium 25 mg enteric tablet, 50**

5076E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*18.89	20.34	<sup>a</sup> Clonac 25 [RW] <sup>a</sup> DICLOFENAC-WGR [WG]	<sup>a</sup> Diclofenac Sandoz [SZ] <sup>a</sup> Fenac EC [AL]
			<sup>B</sup> 4.96	*23.85	20.34	<sup>a</sup> Voltaren 25 [NV]	

**diclofenac sodium 50 mg enteric tablet, 50**

1300K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	3	..	16.37	17.82	<sup>a</sup> Clonac 50 [RW] <sup>a</sup> DICLOFENAC-WGR [WG]	<sup>a</sup> Diclofenac Sandoz [SZ] <sup>a</sup> Fenac EC [AL]
			<sup>B</sup> 4.95	21.32	17.82	<sup>a</sup> Voltaren 50 [NV]	

**diclofenac sodium 50 mg enteric tablet, 50**

5077F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.37	17.82	<sup>a</sup> Clonac 50 [RW] <sup>a</sup> DICLOFENAC-WGR [WG]	<sup>a</sup> Diclofenac Sandoz [SZ] <sup>a</sup> Fenac EC [AL]
			<sup>B</sup> 4.95	21.32	17.82	<sup>a</sup> Voltaren 50 [NV]	

**■ INDOMETACIN****indometacin 100 mg suppository, 20**

2757D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	3	..	*27.45	28.90	Indocid [AS]

**indometacin 100 mg suppository, 20**

5128X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	2	..	..	*27.45	28.90	Indocid [AS]

■ **INDOMETACIN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

2454E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*20.13	21.58	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*24.17	21.58	<sup>a</sup> Indocid [AS]

■ **INDOMETACIN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

5126T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*20.13	21.58	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*24.17	21.58	<sup>a</sup> Indocid [AS]

**Oxicams**■ **MELOXICAM**

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**meloxicam 7.5 mg tablet, 30**

8561N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.97	18.42	<sup>a</sup> APX-Meloxicam [TY]	<sup>a</sup> CIPLA MELOXICAM 7.5 [LR]
						<sup>a</sup> MELOBIC [RF]	<sup>a</sup> Meloxibell [GQ]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> Meloxicam Viatris [AL]
						<sup>a</sup> MELOXICAM-WGR [WG]	<sup>a</sup> Movalis 7.5 [RW]
						<sup>a</sup> Moxicam 7.5 [AF]	
			<sup>B</sup> 2.82	19.79	18.42	<sup>a</sup> Mobic [BY]	

**meloxicam 7.5 mg capsule, 30**

8887R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.97	18.42	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> MELOBIC [RF]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> MELOXICAM-WGR [WG]
						<sup>a</sup> Movalis 7.5 [RW]	<sup>a</sup> Moxicam [AF]
			<sup>B</sup> 2.82	19.79	18.42	<sup>a</sup> Mobic [BY]	

■ **MELOXICAM**

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**meloxicam 15 mg capsule, 30**

8888T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	17.67	19.12	<sup>a</sup> APO-Meloxicam [TX]	<sup>a</sup> MELOBIC [RF]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> MELOXICAM-WGR [WG]
						<sup>a</sup> Movalis 15 [RW]	<sup>a</sup> Moxicam [AF]
			<sup>B</sup> 2.88	20.55	19.12	<sup>a</sup> Mobic [BY]	

**meloxicam 15 mg tablet, 30**

8562P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	17.67	19.12	<sup>a</sup> APX-Meloxicam [TY]	<sup>a</sup> CIPLA MELOXICAM 15 [LR]
						<sup>a</sup> MELOBIC [RF]	<sup>a</sup> Meloxibell [GQ]
						<sup>a</sup> Meloxicam Sandoz [SZ]	<sup>a</sup> Meloxicam Viatris [AL]
						<sup>a</sup> MELOXICAM-WGR [WG]	<sup>a</sup> Movalis 15 [RW]
			<sup>B</sup> 2.88	20.55	19.12	<sup>a</sup> Moxicam 15 [AF]	
						<sup>a</sup> Mobic [BY]	

**PIROXICAM****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**piroxicam 10 mg capsule, 50**

1897W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.02	19.47	APO-Piroxicam [TX]

**piroxicam 10 mg capsule, 50**

5203W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	18.02	19.47	APO-Piroxicam [TX]

**piroxicam 20 mg capsule, 25**

1898X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.83	18.28	APO-Piroxicam [TX]

**piroxicam 20 mg capsule, 25**

5204X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.83	18.28	APO-Piroxicam [TX]

**Propionic acid derivatives****IBUPROFEN****ibuprofen 400 mg tablet, 30**

3192B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.15	17.60	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> WGR-IBUPROFEN 400 [WG]
			<sup>B</sup> 2.51	18.66	17.60	<sup>a</sup> Brufen [GO]	

**ibuprofen 400 mg tablet, 30**

5124Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.15	17.60	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> WGR-IBUPROFEN 400 [WG]
			<sup>B</sup> 2.51	18.66	17.60	<sup>a</sup> Brufen [GO]	

**IBUPROFEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

3190X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	3	..	*21.54	22.99	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> WGR-IBUPROFEN 400 [WG]
			<sup>B</sup> 7.53	*29.07	22.99	<sup>a</sup> Brufen [GO]	

**■ IBUPROFEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

5123P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	3	..	..	*21.54	22.99	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> WGR-IBUPROFEN 400 [WG]
			<sup>B</sup> 7.53	*29.07	22.99	<sup>a</sup> Brufen [GO]	

**■ NAPROXEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

1615B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	20.02	21.47	<sup>a</sup> Proxen SR 1000 [IY]
			<sup>B</sup> 2.35	22.37	21.47	<sup>a</sup> Naprosyn SR1000 [IX]

**naproxen 250 mg tablet, 50**

1674D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*22.91	24.36	Naprosyn [IX]

**naproxen 750 mg modified release tablet, 28**

1614Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.41	19.86	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 2.35	20.76	19.86	<sup>a</sup> Naprosyn SR750 [IX]

**■ NAPROXEN****Authority required (STREAMLINED)****4159**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority required (STREAMLINED)****4124**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**naproxen 125 mg/5 mL oral liquid, 474 mL**

1658G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	124.15	31.60	Phebra Naproxen Suspension [FF]

**■ NAPROXEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 1 g modified release tablet, 28**

5179N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.02	21.47	<sup>a</sup> Proxen SR 1000 [IY]
			<sup>B</sup> 2.35	22.37	21.47	<sup>a</sup> Naprosyn SR1000 [IX]

**naproxen 250 mg tablet, 50**

5176K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*22.91	24.36	Naprosyn [IX]

**naproxen 750 mg modified release tablet, 28**

5178M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	18.41	19.86	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 2.35	20.76	19.86	<sup>a</sup> Naprosyn SR750 [IX]

**■ NAPROXEN**

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

1795L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	19.02	20.47	<sup>a</sup> Crysanal [IY]
			<sup>B</sup> 2.85	21.87	20.47	<sup>a</sup> Anaprox 550 [IX]

**■ NAPROXEN**

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen sodium 550 mg tablet, 50**

5186Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	19.02	20.47	<sup>a</sup> Crysanal [IY]
			<sup>B</sup> 2.85	21.87	20.47	<sup>a</sup> Anaprox 550 [IX]

***Fenamates*****■ MEFENAMIC ACID****Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

**mefenamic acid 250 mg capsule, 50**

1824B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.43	19.88	<sup>a</sup> FEMIN [XT]
			<sup>B</sup> 1.57	20.00	19.88	<sup>a</sup> Ponstan [PF]

***Coxibs*****■ CELECOXIB**

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**celecoxib 100 mg capsule, 60**

8439E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		3	..	17.87	19.32	<sup>a</sup> APX-Celecoxib [TW] <sup>a</sup> Blooms the Chemist Celecoxib [IB] <sup>a</sup> Celebrex [UJ] <sup>a</sup> Celecoxib GH [GQ] <sup>a</sup> CELECOXIB-WGR [WG]	<sup>a</sup> Blooms Celecoxib [BG] <sup>a</sup> Celaxib [AF] <sup>a</sup> Celecoxib APOTEX [TY] <sup>a</sup> Celecoxib Sandoz [SZ] <sup>a</sup> Celexi [RW]

**celecoxib 200 mg capsule, 30**

8440F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		3	..	17.87	19.32	<sup>a</sup> APX-Celecoxib [TW] <sup>a</sup> Blooms the Chemist Celecoxib [IB] <sup>a</sup> Celebrex [UJ] <sup>a</sup> Celecoxib GH [GQ] <sup>a</sup> CELECOXIB-WGR [WG]	<sup>a</sup> Blooms Celecoxib [BG] <sup>a</sup> Celaxib [AF] <sup>a</sup> Celecoxib APOTEX [TY] <sup>a</sup> Celecoxib Sandoz [SZ] <sup>a</sup> Celexi [RW]

**SPECIFIC ANTIRHEUMATIC AGENTS***Quinolines***■ HYDROXYCHLOROQUINE****hydroxychloroquine sulfate 200 mg tablet, 100**

1512N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		1	..	27.52	28.97	<sup>a</sup> APO- Hydroxychloroquine [TX] <sup>a</sup> Hydroxychloroquine GH [GQ]	<sup>a</sup> Hequinel [RW] <sup>a</sup> Plaquenil [SW]

*Gold preparations***■ AURANOFIN****Caution** Regular blood and urine checks are essential.**Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**auranofin 3 mg capsule, 60**

2022K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1		5	..	905.31	31.60	Ridaura [BZ]

**auranofin 3 mg tablet, 60**

1095P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1		5	..	165.80	31.60	Ridaura [GH]

*Penicillamine and similar agents***■ PENICILLAMINE****Caution** Regular blood and urine checks are essential.**Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**penicillamine 125 mg tablet, 100**

2721F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1		1	..	64.41	31.60	D-Penamine [AL]

**penicillamine 250 mg tablet, 100**

2838J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1		1	..	77.47	31.60	D-Penamine [AL]

## ■ PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### penicillamine 125 mg tablet, 100

13458H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	1	..	*115.45	31.60	D-Penamine [AL]	

### penicillamine 250 mg tablet, 100

13425N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	1	..	*142.89	31.60	D-Penamine [AL]	

## ■ MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

#### *Other centrally acting agents*

## ■ BACLOFEN

### baclofen 10 mg tablet, 100

2729P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.44	24.89	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> Lioresal 10 [NV]	<sup>a</sup> Clofen 10 [AF] <sup>a</sup> Stelax 10 [RW]

### baclofen 25 mg tablet, 100

2730Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.27	31.60	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> Lioresal 25 [NV]	<sup>a</sup> Clofen 25 [AF] <sup>a</sup> Stelax 25 [RW]

## ■ BACLOFEN

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### baclofen 10 mg tablet, 100

13522Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*33.43	31.60	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> Lioresal 10 [NV]	<sup>a</sup> Clofen 10 [AF] <sup>a</sup> Stelax 10 [RW]

### baclofen 25 mg tablet, 100

13359D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*57.09	31.60	<sup>a</sup> APO-Baclofen [TX] <sup>a</sup> Lioresal 25 [NV]	<sup>a</sup> Clofen 25 [AF] <sup>a</sup> Stelax 25 [RW]

### MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

#### *Dantrolene and derivatives*

## ■ DANTROLENE

### Restricted benefit

Chronic spasticity

### dantrolene sodium hemiheptahydrate 25 mg capsule, 100

1779P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	2	..	162.81	31.60	Dantrium [PF]	

## ■ ANTIGOUT PREPARATIONS

### ANTIGOUT PREPARATIONS

#### *Preparations inhibiting uric acid production*

## ■ ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**allopurinol 100 mg tablet, 200**

2600W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	18.32	19.77	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> ALLOPURINOL-WGR [WG] <sup>a</sup> APO-ALLOPURINOL [TX]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> Allosig [RF] <sup>a</sup> NOUMED ALLOPURINOL [VO]
			<sup>B</sup> 5.62	23.94	19.77	<sup>a</sup> Progout 100 [AF] <sup>a</sup> Zyloprim [RW]	

**allopurinol 300 mg tablet, 60**

2604C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.22	18.67	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> ALLOPURINOL-WGR [WG] <sup>a</sup> APO-ALLOPURINOL [TX]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> Allosig [RF] <sup>a</sup> NOUMED ALLOPURINOL [VO]
			<sup>B</sup> 5.64	22.86	18.67	<sup>a</sup> Progout 300 [AF] <sup>a</sup> Zyloprim [RW]	

**■ ALLOPURINOL**

**Note** The dose should be adjusted in accordance with renal function.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**allopurinol 100 mg tablet, 200**

13358C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*23.19	24.64	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> ALLOPURINOL-WGR [WG] <sup>a</sup> APO-ALLOPURINOL [TX]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> Allosig [RF] <sup>a</sup> NOUMED ALLOPURINOL [VO]
			<sup>B</sup> 11.24	*34.43	24.64	<sup>a</sup> Progout 100 [AF] <sup>a</sup> Zyloprim [RW]	

**allopurinol 300 mg tablet, 60**

13375L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*20.99	22.44	<sup>a</sup> Allopurinol APOTEX [GX] <sup>a</sup> ALLOPURINOL-WGR [WG] <sup>a</sup> APO-ALLOPURINOL [TX]	<sup>a</sup> Allopurinol Sandoz [SZ] <sup>a</sup> Allosig [RF] <sup>a</sup> NOUMED ALLOPURINOL [VO]
			<sup>B</sup> 11.28	*32.27	22.44	<sup>a</sup> Progout 300 [AF] <sup>a</sup> Zyloprim [RW]	

**■ FEBUXOSTAT****Authority required (STREAMLINED)****8921**

Chronic gout

**Clinical criteria:**

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

10445R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	51.32	31.60	Adenuric [FK]

**■ FEBUXOSTAT****Authority required (STREAMLINED)****14313**

Chronic gout

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.



**febuxostat 80 mg tablet, 28**

13519M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*89.19	31.60	Adenuric [FK]

*Preparations increasing uric acid excretion*■ **PROBENECID****probenecid 500 mg tablet, 100**

1940D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	75.82	31.60	Pro-Cid [FF]

■ **PROBENECID****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**probenecid 500 mg tablet, 100**

13942T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*139.41	31.60	Pro-Cid [FF]

*Preparations with no effect on uric acid metabolism*■ **COLCHICINE****colchicine 500 microgram tablet, 30**

3410L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.15	18.60	<sup>a</sup> Colcine [CR]	<sup>a</sup> Lengout [LN]
			<sup>B</sup> 2.02	19.17	18.60	<sup>a</sup> Colgout [AS]	

■ **DRUGS FOR TREATMENT OF BONE DISEASES****DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION***Bisphosphonates*■ **ALENDRONATE****Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**alendronate 70 mg tablet, 4**

8511Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.37	18.82	<sup>a</sup> Alendronate Sandoz [SZ] <sup>a</sup> APO-Alendronate [TX]	<sup>a</sup> ALENDRONATE-WGR [WG] <sup>a</sup> Fonat [AL]

**■ ALENDRONATE****Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**alendronate 70 mg tablet, 4**

13499L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.29	22.74	<sup>a</sup> Alendronate Sandoz [SZ] <sup>a</sup> APO-Alendronate [TX]	<sup>a</sup> ALENDRONATE-WGR [WG] <sup>a</sup> Fonat [AL]

**■ IBANDRONATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**ibandronate 50 mg tablet, 28**

9357L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	219.38	31.60	Bondronat [IX]

## ■ PAMIDRONATE DISODIUM

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Symptomatic Paget disease of bone

### pamidronate disodium 15 mg/5 mL injection, 5 mL vial

8461H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	..	..	*72.87	31.60	Pamisol [PF]

### pamidronate disodium 30 mg/10 mL injection, 10 mL vial

8462J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*72.89	31.60	Pamisol [PF]

### pamidronate disodium 60 mg/10 mL injection, 10 mL vial

8463K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	72.88	31.60	Pamisol [PF]

## ■ RISEDRONATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Restricted benefit

Symptomatic Paget disease of bone

### risedronate sodium 30 mg tablet, 28

8482K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	180.66	31.60	Actonel [TT]

## ■ RISEDRONATE

#### Restricted benefit

Corticosteroid-induced osteoporosis

#### Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

#### Restricted benefit

Osteoporosis

#### Population criteria:

- Patient must be aged 70 years or older.

#### Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

#### Restricted benefit

Established osteoporosis

#### Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**risedronate sodium 150 mg tablet, 1**

9391G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	35.60	31.60	<sup>a</sup> Actonel Once-a-Month [TT]	<sup>a</sup> APO-Risedronate [TX]

**risedronate sodium 35 mg tablet, 4**

8621R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	33.88	31.60	<sup>a</sup> APO-Risedronate [TX] <sup>a</sup> RISEDRONATE-WGR [WG]	<sup>a</sup> Risedronate Sandoz [SZ]

**risedronate sodium 35 mg enteric tablet, 4**

8972F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	33.88	31.60	Actonel EC [TT]	

**risedronate sodium 5 mg tablet, 28**

8481J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	37.47	31.60	Actonel [TT]	

**■ RISEDRONATE****Restricted benefit**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**risedronate sodium 150 mg tablet, 1**

13488X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*57.75	31.60	<sup>a</sup> Actonel Once-a-Month [TT]	<sup>a</sup> APO-Risedronate [TX]

**risedronate sodium 35 mg tablet, 4**

13459J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*54.31	31.60	<sup>a</sup> APO-Risedronate [TX]	<sup>a</sup> Risedronate Sandoz [SZ]

<sup>a</sup> RISEDRONATE-WGR [WG]**NP Risedronate sodium 35 mg enteric tablet, 4**

13364J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*54.31	31.60	Actonel EC [TT]

**risedronate sodium 5 mg tablet, 28**

13360E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*61.49	31.60	Actonel [TT]

**■ ZOLEDRONIC ACID****Authority required (STREAMLINED)****5710**

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9350D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	74.99	31.60	<sup>a</sup> Aclasta [HX] <sup>a</sup> Zoledasta [TX]	<sup>a</sup> Osteovan [SZ] <sup>a</sup> Zoledronate-RDY 5 [RI]

**■ ZOLEDRONIC ACID**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6308**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
  - Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
  - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
  - Patient must not receive more than one PBS-subsidised treatment per year.
- The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6313**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
  - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
  - Patient must not receive more than one PBS-subsidised treatment per year.
- The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6318**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

9288W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	74.99	31.60	<sup>a</sup> Aclasta [HX] <sup>a</sup> Zoledasta [TX]	<sup>a</sup> Osteovan [SZ] <sup>a</sup> Zoledronate-RDY 5 [RI]

***Bisphosphonates, combinations***

## ■ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### Authority required (STREAMLINED)

**6306**

Corticosteroid-induced osteoporosis

#### **Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

### Authority required (STREAMLINED)

**6325**

Osteoporosis

#### **Population criteria:**

- Patient must be aged 70 years or older.

#### **Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

### Authority required (STREAMLINED)

**6319**

Established osteoporosis

#### **Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### **alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4**

9183H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.63	22.08	Fosamax Plus 70 mg/140 mcg [MQ]

## ■ ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### Authority required (STREAMLINED)

**15032**

Corticosteroid-induced osteoporosis

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

### Authority required (STREAMLINED)

**14898**

Osteoporosis

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **Population criteria:**

- Patient must be aged 70 years or older.

#### **Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****14993**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4**

13835E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*27.81	29.26	Fosamax Plus 70 mg/140 mcg [MQ]

**■ ALENDRONATE + COLECALCIFEROL**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)****6307**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6320**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6315**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4**

9012H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.63	22.08	Fosamax Plus [MQ]

**■ ALENDRONATE + COLECALCIFEROL**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)****15024**

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****15011**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****15035**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4**

14003B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.81	29.26	Fosamax Plus [MQ]

***Other drugs affecting bone structure and mineralization*****■ CALCITRIOL****Authority required (STREAMLINED)****5401**

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)****5255**

Hypoparathyroidism

**Authority required (STREAMLINED)****5089**

Hypophosphataemic rickets

**Authority required (STREAMLINED)****5114**

Vitamin D-resistant rickets

**Authority required (STREAMLINED)****5402**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.



**calcitriol 0.25 microgram capsule, 100**

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	29.58	31.03	<sup>a</sup> Calciprox [ZS]	<sup>a</sup> CALITROL [XT]
						<sup>a</sup> Sical [AF]	
			<sup>B</sup> 2.29	31.87	31.03	<sup>a</sup> Rocaltrol [IX]	

**■ CALCITRIOL****Authority required (STREAMLINED)****14322**

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

**Authority required (STREAMLINED)****14287**

Hypoparathyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14231**

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14296**

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14259**

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

13457G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*45.71	31.60	<sup>a</sup> Calciprox [ZS]	<sup>a</sup> CALITROL [XT]
						<sup>a</sup> Sical [AF]	
			<sup>B</sup> 4.58	*50.29	31.60	<sup>a</sup> Rocaltrol [IX]	

**■ DENOSUMAB**

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4504**

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

10061M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	462.13	31.60	Xgeva [AN]

**■ DENOSUMAB****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4158**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)****4150**

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

5110Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	462.13	31.60	Xgeva [AN]

**■ DENOSUMAB**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6548**

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)****6524**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**denosumab 60 mg/mL injection, 1 mL syringe**

5457F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	251.97	31.60	Prolia [AN]

**■ RALOXIFENE**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****6314**

Established post-menopausal osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**raloxifene hydrochloride 60 mg tablet, 28**

8363E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.30	31.60	<sup>a</sup> Fixta 60 [ZS]	<sup>a</sup> RALOVISTA [RF]
						<sup>a</sup> Raloxifene GH [GQ]	
			<sup>B</sup> 4.09	34.39	31.60	<sup>a</sup> Evista [LY]	

**■ RALOXIFENE**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)****14274**

Established post-menopausal osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**raloxifene hydrochloride 60 mg tablet, 28**

13426P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*47.15	31.60	<sup>a</sup> Fixta 60 [ZS]	<sup>a</sup> RALOVISTA [RF]
						<sup>a</sup> Raloxifene GH [GQ]	
			<sup>B</sup> 8.18	*55.33	31.60	<sup>a</sup> Evista [LY]	

**■ ROMOSUZUMAB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment - Second-line therapy

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy, **AND**
- Patient must not have received treatment with PBS-subsidised teriparatide; OR
- Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment - Second-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes**

12301K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	406.13	31.60	Evenity [AN]

**■ ROMOSOZUMAB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment - First-line therapy

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; OR
- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment - First-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**Authority required**

Severe established osteoporosis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2024, **AND**
- Patient must not have received PBS-subsidised treatment with any of the following prior to initiating non-PBS-subsidised treatment with this drug for this condition: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have had a Bone Mineral Density (BMD) T-score of -2.5 or less prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the 24 months prior to starting non-PBS-subsidised treatment with this drug for this condition; OR

- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the 24 months prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes**

14641N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	406.13	31.60	Evenity [AN]

**■ TERIPARATIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**Authority required (STREAMLINED)****15536**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

14482F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*346.15	31.60	<sup>a</sup> Teriparatide Lupin [GQ]	<sup>a</sup> Terrosa [FX]

**■ TERIPARATIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****12492**

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received treatment with PBS-subsidised romosozumab; OR
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority required (STREAMLINED)**

**12270**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

14093R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	177.30	31.60	<sup>a</sup> Teriparatide Lupin [GQ]	<sup>a</sup> Terrosa [FX]

▪ **VOSORITIDE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Achondroplasia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for FGFR3 gene mutation.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**Authority required**

Achondroplasia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS subsidised vosoritide treatment for this condition, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii)

bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; OR
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**vosoritide 400 microgram injection [10 vials] (& inert substance diluent [10 x 0.5 mL syringes], 1 pack**

13275Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*27840.60	31.60	Voxzogo [IO]

**vosoritide 560 microgram injection [10 vials] (& inert substance diluent [10 x 0.7 mL syringes], 1 pack**

13274P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*27840.60	31.60	Voxzogo [IO]

**vosoritide 1.2 mg injection [10 vials] (& inert substance diluent [10 x 0.6 mL syringes], 1 pack**

13270K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*27840.60	31.60	Voxzogo [IO]

## NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

*Natural opium alkaloids*

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.


**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

12054K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	0.5	..	..	*23.08	24.53	Aspen Pharmacare Australia Pty Ltd [AS]

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.


**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

5063L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	23.20	24.65	Aspen Pharmacare Australia Pty Ltd [AS]

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Restricted benefit**

Severe pain

#### **Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

#### **codeine phosphate hemihydrate 30 mg tablet, 20**

12065B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	..	..	*23.08	24.53	Aspen Pharmacare Australia Pty Ltd [AS]

#### **CODEINE**

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**



Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**codeine phosphate hemihydrate 30 mg tablet, 20**

1214X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.20	24.65	Aspen Pharmacare Australia Pty Ltd [AS]

▪ **HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

12045Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.5	..	..	*24.46	25.91	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

12032G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.5	..	..	*25.86	27.31	Dilaudid [MF]

**hydromorphone hydrochloride 8 mg tablet, 20**

12010D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.5	..	..	*31.08	31.60	Dilaudid [MF]

▪ **HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

5115F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	25.42	26.87	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

5116G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.69	29.14	Dilaudid [MF]

**hydromorphone hydrochloride 8 mg tablet, 20**

5117H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	36.10	31.60	Dilaudid [MF]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL**

14080C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	435.42	31.60	pms-HYDROmorphine [DZ]

**■ HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

12047C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	..	..	*24.46	25.91	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

12046B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	..	..	*25.86	27.31	Dilaudid [MF]

**hydromorphone hydrochloride 8 mg tablet, 20**

12016K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	..	..	*31.08	31.60	Dilaudid [MF]

**■ HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

12559B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	434.30	31.60	<sup>a</sup> Hikma [LM]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

13799G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	435.42	31.60	<sup>a</sup> Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

**■ HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857  
[Your capital city]

### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats must only be considered for:
- (i) severe disabling pain associated with proven malignant neoplasia; or
  - (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

8421F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	26.92	28.37	<sup>a</sup> Dilaudid-HP [MF] <sup>a</sup> HYDROMORPHONE JUNO-HP [JU]	<sup>a</sup> Hydromorphone-hameln-HP [HW] <sup>a</sup> MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ]

### hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

8420E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.89	26.34	<sup>a</sup> Dilaudid [MF] <sup>a</sup> HYDROMORPHONE JUNO [JU]	<sup>a</sup> Hydromorphone-hameln [HW] <sup>a</sup> MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ]

### hydromorphone hydrochloride 2 mg tablet, 20

8541M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.42	26.87	Dilaudid [MF]

### hydromorphone hydrochloride 4 mg tablet, 20

8542N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.69	29.14	Dilaudid [MF]

### hydromorphone hydrochloride 8 mg tablet, 20

8543P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	36.10	31.60	Dilaudid [MF]

### hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14076W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	435.42	31.60	pms-HYDROMORPHONE [DZ]

## ■ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Note** Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

#### Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats must only be considered for:
- (i) severe disabling pain associated with proven malignant neoplasia; or
  - (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

12582F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	434.30	31.60	<sup>a</sup> Hikma [LM]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

13796D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	435.42	31.60	<sup>a</sup> Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

**▪ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

12067D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.5	..	..	*27.55	29.00	Anamorph [RW]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

10858L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	25.16	26.61	Morphine Juno [JU]

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

5169C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	26.55	28.00	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

5170D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	28.65	30.10	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

5163R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	30.41	31.60	Anamorph [RW]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

12009C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	..	..	*27.55	29.00	Anamorph [RW]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate 2 mg/mL oral solution, 100 mL**

13747M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*110.28	31.60	<sup>a</sup> Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

**morphine sulfate 2 mg/mL oral solution, 500 mL**

13760F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.4	..	..	*76.66	31.60	<sup>a</sup> Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

**morphine sulfate 10 mg/5 mL oral solution, 100 mL**

13750Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*148.74	31.60	<sup>a</sup> Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

**morphine sulfate 10 mg/5 mL oral solution, 300 mL**

13740E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.67	..	..	*95.46	31.60	<sup>a</sup> Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

10863R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.97	24.42	<sup>a</sup> Morphine Juno [JU]

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

5168B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.79	25.24	<sup>a</sup> MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

14203M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	104.85	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

5238Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	104.85	31.60	<sup>a</sup> Ordine 5 [XT]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

#### **Restricted benefit**

Severe pain

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### **morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

5237P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	61.84	31.60	<sup>a</sup> Ordine 2 [XT]

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand Morphini HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

#### **Restricted benefit**

Severe pain

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### **morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

14204N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	154.95	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

#### **morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

5239R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	154.95	31.60	<sup>a</sup> Ordine 10 [XT]

#### **morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL**

14077X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	..	..	*566.44	31.60	<sup>a</sup> Morphini HCl Streuli [DZ]

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).



**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10874H	1	..	..	25.16	26.61	Morphine Juno [JU]

NP

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1645N	1	..	..	26.55	28.00	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

NP

MW

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1647Q	1	..	..	28.65	30.10	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

NP

**morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

10869C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	30.96	31.60	Morphine Juno [JU]

**morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules**

10878M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	37.01	31.60	Morphine Juno [JU]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### morphine sulfate pentahydrate 200 mg modified release tablet, 28

12055L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	121.43	31.60	MS Contin [MF]

## ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

### Restricted benefit

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### Restricted benefit

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through

consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Cancer pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  
(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **morphine sulfate pentahydrate 30 mg tablet, 20**

14654G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.41	31.60	Anamorph [RW]

#### **morphine sulfate pentahydrate 10 mg tablet, 20**

8669G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.35	24.80	Sevredol [MF]

#### **morphine sulfate pentahydrate 20 mg tablet, 20**

8670H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.10	25.55	Sevredol [MF]

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- severe disabling pain associated with malignant neoplasia; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **morphine sulfate pentahydrate 30 mg tablet, 20**

1646P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	30.41	31.60	Anamorph [RW]

## **■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

## **Authority required (STREAMLINED)**

**10755**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

## **Authority required (STREAMLINED)**

**10748**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

## **Authority required (STREAMLINED)**

**10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### morphine sulfate pentahydrate 30 mg modified release tablet, 28

1654C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	36.32	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> Morphine MR Mylan [AF]	<sup>a</sup> MS Contin [MF]

### morphine sulfate pentahydrate 5 mg modified release tablet, 28

8035X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.60	27.05	MS Contin [MF]

### morphine sulfate pentahydrate 60 mg modified release tablet, 28

1655D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	49.54	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> Morphine MR Mylan [AF]	<sup>a</sup> MS Contin [MF]

### morphine sulfate pentahydrate 10 mg modified release capsule, 28

8349K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.31	29.76	Kapanol [YN]

### morphine sulfate pentahydrate 100 mg modified release capsule, 28

2841M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	60.75	31.60	Kapanol [YN]

### morphine sulfate pentahydrate 120 mg modified release capsule, 14

8494C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.53	31.60	MS Mono [MF]

### morphine sulfate pentahydrate 20 mg modified release capsule, 28

2839K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.21	30.66	Kapanol [YN]

### morphine sulfate pentahydrate 30 mg modified release capsule, 14

8491X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.69	30.14	MS Mono [MF]

### morphine sulfate pentahydrate 50 mg modified release capsule, 28

2840L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.17	31.60	Kapanol [YN]

### morphine sulfate pentahydrate 60 mg modified release capsule, 14

8492Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	36.30	31.60	MS Mono [MF]

### morphine sulfate pentahydrate 90 mg modified release capsule, 14

8493B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	39.95	31.60	MS Mono [MF]

### morphine sulfate pentahydrate 10 mg modified release tablet, 28

1653B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	25.97	27.42	<sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> Morphine MR Mylan [AF]	<sup>a</sup> MS Contin [MF]

### morphine sulfate pentahydrate 100 mg modified release tablet, 28

1656E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	62.15	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX] <sup>a</sup> Morphine MR Mylan [AF]	<sup>a</sup> MS Contin [MF]

### morphine sulfate pentahydrate 15 mg modified release tablet, 28

8489T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.96	31.60	MS Contin [MF]

## ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

8453X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	121.43	31.60	MS Contin [MF]

▪ **MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.



Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **morphine sulfate 2 mg/mL oral solution, 100 mL**

13753W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*110.28	31.60	<sup>a</sup> Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

#### **morphine sulfate 2 mg/mL oral solution, 500 mL**

13749P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.4	..	..	*76.66	31.60	<sup>a</sup> Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

#### **morphine sulfate 10 mg/5 mL oral solution, 100 mL**

13761G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*148.74	31.60	<sup>a</sup> Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

#### **morphine sulfate 10 mg/5 mL oral solution, 300 mL**

13756B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.67	..	..	*95.46	31.60	<sup>a</sup> Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- severe disabling pain associated with malignant neoplasia; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

10864T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	22.97	24.42	<sup>a</sup> Morphine Juno [JU]

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

1644M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	23.79	25.24	<sup>a</sup> MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

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**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

14220K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	104.85	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

### morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

2123R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	104.85	31.60	<sup>a</sup> Ordine 5 [XT]

## ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Pharmaceutical benefits that have the brand Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) and Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL may be substituted for pharmaceutical benefits that have the brand Ordine 2 in case of shortage.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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[Your capital city]

#### Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### Restricted benefit

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR

- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for:
  - (i) severe disabling pain associated with proven malignant neoplasia; or
  - (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

2122Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	61.84	31.60	<sup>a</sup> Ordine 2 [XT]

## **■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand Morphini HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats must only be considered for:
- severe disabling pain associated with proven malignant neoplasia; or
  - palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
- severe disabling pain associated with malignant neoplasia; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  - palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

14194C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	154.95	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

NP

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2124T	1	..	..	154.95	31.60	<sup>a</sup> Ordine 10 [XT]

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14083F	10	..	..	*566.44	31.60	<sup>a</sup> Morphini HCl Streuli [DZ]

**■ OXYCODONE****Caution** The risk of drug dependence is high.**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg capsule, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12311Y	1	..	..	21.74	23.19	OxyNorm [MF]

**oxycodone hydrochloride 5 mg tablet, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13234M	1	..	..	20.49	21.94	<sup>a</sup> Oxycodone Viatris [MQ]
			<sup>B</sup> 1.00	21.49	21.94	<sup>a</sup> ENDONE [AF]

**oxycodone hydrochloride 10 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12074L	0.5	..	..	*23.28	24.73	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

**■ OXYCODONE****Caution** The risk of drug dependence is high.**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5197M	1	..	..	23.52	24.97	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

**oxycodone hydrochloride 5 mg capsule, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5191F	1	..	..	24.24	25.69	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5190E	1	..	..	32.07	31.60	OxyNorm Liquid 1mg/mL [MF]

**oxycodone hydrochloride 5 mg tablet, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5195K	1	..	..	21.74	23.19	<sup>a</sup> Mayne Pharma Oxycodone IR [SZ]	<sup>a</sup> Oxycodone Viatris [MQ]
			<sup>B</sup> 2.00	23.74	23.19	<sup>a</sup> Oxyndone [TX]	<sup>a</sup> ENDONE [AF]

**■ OXYCODONE****Caution** The risk of drug dependence is high.**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for post-operative pain following a major operative procedure, **AND**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone 30 mg suppository, 12**

5194J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	51.18	31.60	Proladone [FF]

**■ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

12031F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.5	..	..	*23.28	24.73	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

**■ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

**oxycodone hydrochloride 5 mg capsule, 10**

12314D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	21.74	23.19	OxyNorm [MF]

**oxycodone hydrochloride 5 mg tablet, 10**

13233L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	20.49	21.94	<sup>a</sup> Oxycodone Viatris [MQ]
			<sup>B</sup> 1.00	21.49	21.94	<sup>a</sup> ENDONE [AF]

**■ OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.



Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- severe disabling pain associated with malignant neoplasia; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **oxycodone 30 mg suppository, 12**

2481N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	51.18	31.60	Proladone [FF]

## ■ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
  - Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

- severe disabling pain associated with proven malignant neoplasia; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- severe disabling pain associated with malignant neoplasia; or
- chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### oxycodone hydrochloride 10 mg capsule, 20

8501K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	23.52	24.97	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

#### oxycodone hydrochloride 20 mg capsule, 20

8502L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	26.87	28.32	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

#### oxycodone hydrochloride 5 mg capsule, 20

8464L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.24	25.69	<sup>a</sup> Oxycodone BNM [BZ]	<sup>a</sup> OxyNorm [MF]

#### oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

8644Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	32.07	31.60	OxyNorm Liquid 1mg/mL [MF]	

#### oxycodone hydrochloride 5 mg tablet, 20

2622B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	21.74	23.19	<sup>a</sup> Mayne Pharma Oxycodone IR [SZ]	<sup>a</sup> Oxycodone Viatris [MQ]
						<sup>a</sup> Oxycodone [TX]	
			<sup>b</sup> 2.00	23.74	23.19	<sup>a</sup> ENDONE [AF]	

### ■ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

#### **Authority required (STREAMLINED)**

##### **10755**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Authority required (STREAMLINED)**

**10748**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg modified release tablet, 28**

8385H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	29.83	31.28	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 15 mg modified release tablet, 28**

9399Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	38.07	31.60	OxyContin [MF]

**oxycodone hydrochloride 20 mg modified release tablet, 28**

8386J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	38.31	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 30 mg modified release tablet, 28**

9400R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	51.65	31.60	OxyContin [MF]

**oxycodone hydrochloride 40 mg modified release tablet, 28**

8387K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	48.29	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 80 mg modified release tablet, 28**

8388L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	67.10	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**■ OXYCODONE + NALOXONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)****10755**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****10748**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

11102H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	84.45	31.60	Targin 60/30 [MF]

#### oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

11111T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.94	31.60	Targin 80/40 [MF]

#### oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28

10776E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.69	30.14	Targin 2.5/1.25 mg [MF]

#### oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28

10757E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.91	31.60	Targin 15/7.5mg [MF]

#### oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28

10758F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	58.20	31.60	Targin 30/15 mg [MF]

#### oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28

8934F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	37.56	31.60	Targin 10/5mg [MF]

#### oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28

8935G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	52.05	31.60	Targin 20/10mg [MF]

#### oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28

8936H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	69.05	31.60	Targin 40/20mg [MF]

#### oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28

8000C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	36.43	31.60	Targin 5/2.5mg [MF]

### Phenylpiperidine derivatives

#### ■ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

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[Your capital city]

### **Authority required (STREAMLINED)**

#### **15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Authority required (STREAMLINED)**

#### **15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **Authority required (STREAMLINED)**

#### **16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### fentanyl 12 microgram/hour patch, 5

5265D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.00	25.45	<sup>a</sup> Denpax [AF]

#### fentanyl 12 microgram/hour patch, 5

5437E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.22	26.67	<sup>a</sup> Fenpatch 12 [RW]

#### fentanyl 12 microgram/hour patch, 5

8878G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.00	25.45	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 12 [JC]

### ■ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

#### **Authority required (STREAMLINED)**

##### **15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

##### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

##### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.



Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or


(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 25 microgram/hour patch, 5**

5277R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	25.41	26.86	<sup>a</sup> Denpax [AF]

**fentanyl 25 microgram/hour patch, 5**

5438F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	26.96	28.41	<sup>a</sup> Fenpatch 25 [RW]

**fentanyl 25 microgram/hour patch, 5**

8891Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	25.41	26.86	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 25 [JC]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)****15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

- (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Authority required (STREAMLINED)**

#### **16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **fentanyl 50 microgram/hour patch, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5278T	1	..	..	30.92	31.60	<sup>a</sup> Denpax [AF]

NP

#### **fentanyl 50 microgram/hour patch, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5439G	1	..	..	33.76	31.60	<sup>a</sup> Fenpatch 50 [RW]

NP

#### **fentanyl 50 microgram/hour patch, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8892B	1	..	..	30.92	31.60	<sup>a</sup> APO-Fentanyl [TX]	<sup>a</sup> Durogesic 50 [JC]
						<sup>a</sup> Fentanyl Sandoz [SZ]	

NP

### **■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)**

**15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### fentanyl 75 microgram/hour patch, 5

5279W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	35.39	31.60	<sup>a</sup> Denpax [AF]

### fentanyl 75 microgram/hour patch, 5

5440H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	39.30	31.60	<sup>a</sup> Fenpatch 75 [RW]

### fentanyl 75 microgram/hour patch, 5

8893C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	35.39	31.60	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 75 [JC]

## ■ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

### Authority required (STREAMLINED)

**15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### **Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### Authority required (STREAMLINED)

**15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  
(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 100 microgram/hour patch, 5**

5280X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	39.38	31.60	<sup>a</sup> Denpax [AF]

**fentanyl 100 microgram/hour patch, 5**

5441J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	44.01	31.60	<sup>a</sup> Fenpatch 100 [RW]

**fentanyl 100 microgram/hour patch, 5**

8894D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	39.38	31.60	<sup>a</sup> APO-Fentanyl [TX]	<sup>a</sup> Durogesic 100 [JC]

**NP** Diphenylpropylamine derivatives**■ METHADONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)****15996**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****15994**

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**16000**

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**methadone hydrochloride 10 mg tablet, 20**

1609Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	24.13	25.58	<sup>a</sup> METHADONE-AFT [AE]	<sup>a</sup> Physeptone [AS]

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials**

14202L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	54.27	31.60	Physeptone [AS]

**Oripavine derivatives**

▪ **BUPRENORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)**

**10755**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.



Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10748**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**buprenorphine 15 microgram/hour patch, 2**

10770W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	36.08	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 25 microgram/hour patch, 2**

10756D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	43.25	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 30 microgram/hour patch, 2**

10755C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	46.73	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 40 microgram/hour patch, 2**

10746N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	53.72	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 10 microgram/hour patch, 2**

8866P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	32.40	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 20 microgram/hour patch, 2**

8867Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	39.76	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 5 microgram/hour patch, 2**

8865N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	26.37	27.82	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

*Opioids in combination with non-opioid analgesics***■ PARACETAMOL + CODEINE****Caution** The risk of drug dependence is high.**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

12066C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	0.5	..	..	*16.80	18.25	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX] <sup>a</sup> Codalgin Forte [AF] <sup>a</sup> Comfarol Forte [SZ]  <sup>a</sup> Prodeine Forte [AV]	<sup>a</sup> APX-Paracetamol/Codeine [TY] <sup>a</sup> Codapane Forte 500/30 [AL] <sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]
			<sup>B</sup> 2.05	*18.85	18.25	<sup>a</sup> Panadeine Forte [SW]	

**■ PARACETAMOL + CODEINE****Caution** The risk of drug dependence is high.**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

3316M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	16.37	17.82	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX] <sup>a</sup> Codalgin Forte [AF] <sup>a</sup> Comfarol Forte [SZ]  <sup>a</sup> Prodeine Forte [AV]	<sup>a</sup> APX-Paracetamol/Codeine [TY] <sup>a</sup> Codapane Forte 500/30 [AL] <sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]
			<sup>B</sup> 3.30	19.67	17.82	<sup>a</sup> Panadeine Forte [SW]	

**■ PARACETAMOL + CODEINE****Caution** The risk of drug dependence is high.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

12022R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	0.5	..	..	*16.80	18.25	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX]	<sup>a</sup> APX-Paracetamol/Codeine [TY]
						<sup>a</sup> Codalgin Forte [AF]	<sup>a</sup> Codapane Forte 500/30 [AL]
						<sup>a</sup> Comfarol Forte [SZ]	<sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]
						<sup>a</sup> Prodeine Forte [AV]	
			<sup>B</sup> 2.05	*18.85	18.25	<sup>a</sup> Panadeine Forte [SW]	

**■ PARACETAMOL + CODEINE**

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
 Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  
 Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
 Pharmaceutical Benefits Scheme  
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 [Your capital city]

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
  - Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
  - Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats must only be considered for:
- severe disabling pain associated with proven malignant neoplasia; or
  - palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

1215Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.37	17.82	<sup>a</sup> APO- Paracetamol/Codeine 500/30 [TX]	<sup>a</sup> APX-Paracetamol/Codeine [TY]
						<sup>a</sup> Codalgin Forte [AF]	<sup>a</sup> Codapane Forte 500/30 [AL]
						<sup>a</sup> Comfarol Forte [SZ]	<sup>a</sup> Paracetamol/Codeine GH 500/30 [GQ]
						<sup>a</sup> Prodeine Forte [AV]	
						<sup>a</sup> Panadeine Forte [SW]	
			<sup>b</sup> 3.30	19.67	17.82		

**Other opioids****▪ TAPENTADOL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)****10755**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)****10748**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tapentadol 100 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10094G	1	..	..	36.24	31.60	Palexia SR [CS]

NP

**tapentadol 150 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10100N	1	..	..	43.05	31.60	Palexia SR [CS]

NP

**tapentadol 200 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10091D	1	..	..	49.09	31.60	Palexia SR [CS]

NP

**tapentadol 250 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10092E	1	..	..	54.19	31.60	Palexia SR [CS]

NP

**tapentadol 50 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10096J	1	..	..	29.14	30.59	Palexia SR [CS]

NP

## ■ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

12024W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	0.5	..	..	*16.80	18.25	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> TRAMADOL-WGR [WG] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>B</sup> 1.40	*18.20	18.25	<sup>a</sup> Tramal [CS]	

## ■ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

5232J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> TRAMADOL-WGR [WG] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>B</sup> 2.25	18.62	17.82	<sup>a</sup> Tramal [CS]	

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

5231H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.02	18.47	<sup>a</sup> Tramadol AN [JU] <sup>a</sup> Tramal 100 [CS]	<sup>a</sup> Tramadol Sandoz [SZ]

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

5150C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	19.80	21.25	Tramal [CS]

## ■ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

**tramadol hydrochloride 50 mg capsule, 20**

12008B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	0.5	..	..	*16.80	18.25	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> TRAMADOL-WGR [WG] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>B</sup> 1.40	*18.20	18.25	<sup>a</sup> Tramal [CS]	

## ■ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
 Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  
 Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
 Pharmaceutical Benefits Scheme  
 Reply Paid 9857  
 [Your capital city]

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
  - Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### **Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
  - Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
- Authorities for increased maximum quantities and/or repeats must only be considered for:
- severe disabling pain associated with proven malignant neoplasia; or
  - palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
- severe disabling pain associated with malignant neoplasia; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  - palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### tramadol hydrochloride 50 mg capsule, 20

8455B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.37	17.82	<sup>a</sup> APO-Tramadol [TX] <sup>a</sup> TRAMADOL-WGR [WG] <sup>a</sup> Zydol [RW]	<sup>a</sup> Tramadol Sandoz [SZ] <sup>a</sup> Tramedo [AF]
			<sup>B</sup> 2.25	18.62	17.82	<sup>a</sup> Tramal [CS]	

### tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

8582Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.02	18.47	<sup>a</sup> Tramadol AN [JU] <sup>a</sup> Tramal 100 [CS]	<sup>a</sup> Tramadol Sandoz [SZ]

### tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

8843K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	19.80	21.25	Tramal [CS]

## ■ TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

### Authority required (STREAMLINED)

#### 10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

#### Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### Authority required (STREAMLINED)

#### 10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

#### Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:



- (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **Authority required (STREAMLINED)**

#### **10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### **tramadol hydrochloride 100 mg modified release tablet, 20**

8523N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.61	18.06	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Tramedo SR [AL]	<sup>a</sup> Tramadol Sandoz SR [SZ] <sup>a</sup> TRAMADOL-WGR SR [WG] <sup>a</sup> Zydol SR 100 [RW]
			<sup>B</sup> 4.29	20.90	18.06	<sup>a</sup> Tramal SR 100 [CS]	

#### **tramadol hydrochloride 150 mg modified release tablet, 20**

8524P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.37	18.82	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Tramedo SR [AL]	<sup>a</sup> Tramadol Sandoz SR [SZ] <sup>a</sup> TRAMADOL-WGR SR [WG] <sup>a</sup> Zydol SR 150 [RW]
			<sup>B</sup> 5.23	22.60	18.82	<sup>a</sup> Tramal SR 150 [CS]	

#### **tramadol hydrochloride 200 mg modified release tablet, 20**

8525Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.53	18.98	<sup>a</sup> APO-Tramadol SR [TX] <sup>a</sup> Tramadol SR generichealth [GQ] <sup>a</sup> Tramedo SR [AL]	<sup>a</sup> Tramadol Sandoz SR [SZ] <sup>a</sup> TRAMADOL-WGR SR [WG] <sup>a</sup> Zydol SR 200 [RW]
			<sup>B</sup> 5.95	23.48	18.98	<sup>a</sup> Tramal SR 200 [CS]	

#### **tramadol hydrochloride 50 mg modified release tablet, 20**

2527B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	17.30	18.75	Tramal SR 50 [CS]

### **OTHER ANALGESICS AND ANTIPYRETICS**

#### *Anilides*

#### **■ PARACETAMOL**

##### **Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 48 mg/mL oral liquid, 200 mL

1770E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	17.31	18.76	Panamax 240 Elixir [SW]

### paracetamol 500 mg tablet, 100

1746X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.13	16.58	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

## ■ PARACETAMOL

### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 48 mg/mL oral liquid, 200 mL

3349G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	17.31	18.76	Panamax 240 Elixir [SW]

### paracetamol 500 mg tablet, 100

5196L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.13	16.58	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

## ■ PARACETAMOL

### Restricted benefit

Chronic arthropathies

### Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

### paracetamol 500 mg tablet, 100

5224Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	3	..	..	*18.48	19.93	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

## ■ PARACETAMOL

### Restricted benefit

Chronic arthropathies

### Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

### paracetamol 500 mg tablet, 100

8784H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	4	..	*18.48	19.93	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

## ■ PARACETAMOL

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

### Restricted benefit

Persistent pain

### Clinical criteria:

- The condition must be associated with osteoarthritis.

### Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

**paracetamol 665 mg modified release tablet, 96**

8814X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	<sup>a</sup> APOHEALTH Osteo Relief Paracetamol 665 mg [TX] <sup>a</sup> Parapane OSTEO [XT]	<sup>a</sup> Osteomol 665 Paracetamol [CR]

**paracetamol 665 mg modified release tablet, 192**

10797G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.99	22.44	<sup>a</sup> Osteomol 665 Paracetamol [CR]	<sup>a</sup> Parapane OSTEO [XT]

**Gabapentinoids****■ PREGABALIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4172**

Neuropathic pain

**Clinical criteria:**

- The condition must be refractory to treatment with other drugs.

**pregabalin 150 mg capsule, 56**

2355Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.19	22.64	<sup>a</sup> APO-Pregabalin [TX] <sup>a</sup> BTC Pregabalin [BG] <sup>a</sup> Neuroccord [CR] <sup>a</sup> PREGABALIN-DRLA [RZ] <sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Blooms The Chemist Pregabalin [IB] <sup>a</sup> Lyzalon [AF] <sup>a</sup> Prebalin [RF] <sup>a</sup> Pregabalin Lupin [HQ] <sup>a</sup> PREGABALIN-WGR [WG]
			<sup>B</sup> 8.11	29.30	22.64	<sup>a</sup> Lyrica [UJ]	

**pregabalin 25 mg capsule, 56**

2348N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.60	19.05	<sup>a</sup> APO-Pregabalin [TX] <sup>a</sup> BTC Pregabalin [BG] <sup>a</sup> Neuroccord [CR] <sup>a</sup> PREGABALIN-DRLA [RZ] <sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Blooms The Chemist Pregabalin [IB] <sup>a</sup> Lyzalon [AF] <sup>a</sup> Prebalin [RF] <sup>a</sup> Pregabalin Lupin [HQ] <sup>a</sup> PREGABALIN-WGR [WG]
			<sup>B</sup> 2.00	19.60	19.05	<sup>a</sup> Lyrica [UJ]	

**pregabalin 300 mg capsule, 56**

2363J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.99	26.44	<sup>a</sup> APO-Pregabalin [TX] <sup>a</sup> BTC Pregabalin [BG] <sup>a</sup> Neuroccord [CR] <sup>a</sup> PREGABALIN-DRLA [RZ] <sup>a</sup> Pregabalin Sandoz [SZ]	<sup>a</sup> Blooms The Chemist Pregabalin [IB] <sup>a</sup> Lyzalon [AF] <sup>a</sup> Prebalin [RF] <sup>a</sup> Pregabalin Lupin [HQ] <sup>a</sup> PREGABALIN-WGR [WG]
			<sup>B</sup> 2.00	26.99	26.44	<sup>a</sup> Lyrica [UJ]	

**pregabalin 75 mg capsule, 56**

2335X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.55	20.00	<sup>a</sup> APO-Pregabalin [TX] <sup>a</sup> Lyzalon [AF] <sup>a</sup> Prebalin [RF] <sup>a</sup> Pregabalin Lupin [HQ] <sup>a</sup> PREGABALIN-WGR [WG]	<sup>a</sup> BTC Pregabalin [BG] <sup>a</sup> Neuroccord [CR] <sup>a</sup> PREGABALIN-DRLA [RZ] <sup>a</sup> Pregabalin Sandoz [SZ]
			<sup>B</sup> 6.15	24.70	20.00	<sup>a</sup> Lyrica [UJ]	

**ANTIMIGRAINE PREPARATIONS****Selective serotonin (5HT<sub>1</sub>) agonists****■ ELETRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**eletriptan 40 mg tablet, 4**

5290K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.09	28.54	Relpax [UJ]

**eletriptan 80 mg tablet, 4**

5291L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.09	28.54	Relpax [UJ]

**■ NARATRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**naratriptan 2.5 mg tablet, 2**

8298R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	<sup>S</sup> 1.54	*25.71	25.62	Naramig [AS]

**■ NARATRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority required**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**naratriptan 2.5 mg tablet, 2**

9734H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.71	27.16	Naramig [AS]

**■ RIZATRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**rizatriptan 10 mg orally disintegrating tablet, 2**

10551H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	<sup>a</sup> APO-RIZATRIPTAN ODT [TW] <sup>a</sup> RIXALT [RF]	
						<sup>a</sup> Rizatriptan ODT APOTEX [GX] <sup>a</sup> RIZATRIPTAN ODT-WGR [WG]	

**rizatriptan 10 mg wafer, 2**

9313E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	<sup>B</sup> 2.74	*24.81	23.52	<sup>a</sup> Rizatriptan Wafers-10mg [AF]
			<sup>B</sup> 3.92	*25.99	23.52	<sup>a</sup> Maxalt [AL]

**■ SUMATRIPTAN**

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**sumatriptan 50 mg tablet, 2**

8144P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.71	21.16	<sup>a</sup> APO-Sumatriptan [TX] <sup>a</sup> Iptam [AL]	
						<sup>a</sup> Sumagrain Migraine Relief [GQ] <sup>a</sup> Sumatran [OW]	
			<sup>B</sup> 4.18	*23.89	21.16	<sup>a</sup> Imigran [LN] <sup>a</sup> IMIGRAN MIGRAINE [AS]	

**SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

10694W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 4.19	23.89	21.15	<sup>a</sup> Imigran FDT [AS]

**sumatriptan 50 mg tablet, 4**

1849H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.70	21.15	<sup>a</sup> APO-Sumatriptan [TX] <sup>a</sup> Iptam [AL]	
						<sup>a</sup> Pharmacor Sumatriptan 50 [CR] <sup>a</sup> Sumatran [OW]	
						<sup>a</sup> Sumatriptan generichealth [GQ] <sup>a</sup> Sumatriptan Sandoz [SZ]	
						<sup>a</sup> SUMATRIPTAN-WGR [WG]	

<sup>B</sup>4.19      23.89      21.15      <sup>a</sup> Imigran [LN]

## ■ ZOLMITRIPTAN

**Caution** Selective serotonin (5HT<sub>1</sub>) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

### zolmitriptan 2.5 mg tablet, 2

8266C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.35	26.80	<sup>a</sup> APO-Zolmitriptan [TX]	<sup>a</sup> Zoltrip [RW]
			<sup>B</sup> 4.50	*29.85	26.80	<sup>a</sup> Zomig [AS]	

### Calcitonin gene-related peptide (CGRP) antagonists

## ■ EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**16018**

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.
- Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

### eptinezumab 100 mg/mL injection, 1 mL vial

13342F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1448.78	31.60	Vyepti [LU]

## ■ EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**12029**

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
  - Patient must continue to be appropriately managed for medication overuse headache.
- Patient must have the number of migraine days per month documented in their medical records.

**eptinezumab 100 mg/mL injection, 1 mL vial**

13352R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1448.78	31.60	Vyepti [LU]

**■ FREMANEZUMAB**

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****14563**

Treatment-resistant migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month, **AND**
  - Patient must continue to be appropriately managed for medication overuse headache.
- Patient must have the number of migraine headache days per month documented in their medical records.

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe**

12603H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.39	31.60	<sup>a</sup> Ajovy [TB]

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device**

13129B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	560.39	31.60	<sup>a</sup> Ajovy [TB]

**■ FREMANEZUMAB**

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****16104**

Treatment-resistant migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine headache days per month documented in their medical records.

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe**

12611R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.39	31.60	<sup>a</sup> Ajovy [TB]

**fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device**

13115G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	560.39	31.60	<sup>a</sup> Ajovy [TB]

**■ GALCANEZUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****12029**

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
  - Patient must continue to be appropriately managed for medication overuse headache.
- Patient must have the number of migraine days per month documented in their medical records.

**galcanezumab 120 mg/mL injection, 1 mL pen device**

12469G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	523.03	31.60	Emgality [LY]

**■ GALCANEZUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****16018**

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

**galcanezumab 120 mg/mL injection, 1 mL pen device**

12478R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*1037.61	31.60	Emgality [LY]

***Other antimigraine preparations*****■ PIZOTIFEN**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.



**pizotifen 500 microgram tablet, 100**

3074T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	25.07	26.52	Sandomigran 0.5 [AE]

**PIZOTIFEN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pizotifen 500 microgram tablet, 100**

13866T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*36.69	31.60	Sandomigran 0.5 [AE]

**ANTIEPILEPTICS****ANTIEPILEPTICS***Barbiturates and derivatives***PHENOBARBITAL****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**phenobarbital 30 mg tablet, 200**

1850J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	19.07	20.52	Phenobarb [RW]

**phenobarbital 200 mg (equivalent to phenobarbital sodium 219 mg)/mL injection, 5 x 1 mL ampoules**

2138M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	36.49	31.60	Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd) [AS]

**PRIMIDONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**primidone 250 mg tablet, 200**

1939C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	70.36	31.60	Mysoline [LM]

*Hydantoin derivatives***PHENYTOIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

2692Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	26.58	28.03	Dilantin [UJ]

**phenytoin 50 mg chewable tablet, 200**

1249R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	65.64	31.60	Dilantin Infatabs [UJ]

**phenytoin sodium 100 mg capsule, 200**

1874P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	33.78	31.60	Dilantin Sodium [UJ]

**phenytoin sodium 30 mg capsule, 200**

1873N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	53.03	31.60	Dilantin Sodium [UJ]

**■ PHENYTOIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

13841L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	3	..	*39.71	31.60	Dilantin [UJ]

**phenytoin 50 mg chewable tablet, 200**

13894G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*118.03	31.60	Dilantin Infatabs [UJ]

**phenytoin sodium 100 mg capsule, 200**

13972J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*54.11	31.60	Dilantin Sodium [UJ]

**phenytoin sodium 30 mg capsule, 200**

14015P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*92.61	31.60	Dilantin Sodium [UJ]

*Succinimide derivatives***■ ETHOSUXIMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

1414K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	74.05	31.60	Zarontin [IX]

**■ ETHOSUXIMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 100, and pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 56 are equivalent for the purposes of substitution.

**ethosuximide 250 mg capsule, 100**

11703Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*296.33	31.60	<sup>a</sup> ZARONTIN [IX]

**ethosuximide 250 mg capsule, 56**

13127X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3.57	2	..	*306.67	31.60	<sup>a</sup> Ethosuximide Essential Generics (UK) [IX]

**■ ETHOSUXIMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

14014N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*135.69	31.60	Zarontin [IX]

**Benzodiazepine derivatives****CLONAZEPAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Epilepsy

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

1807D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	24.03	25.48	Rivotril [PB]

**CLONAZEPAM**

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

1808E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*20.99	22.44	Rivotril [PB]

**clonazepam 2 mg tablet, 100**

1806C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*32.45	31.60	Paxam 2 [AF]

**CLONAZEPAM**

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note** Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**clonazepam 500 microgram tablet, 50**

11559J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	2	<sup>B</sup> 3.68	*30.71	28.48	<sup>a</sup> Rivotril [PB]

**clonazepam 500 microgram tablet, 100**

1805B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*27.01	28.46	<sup>a</sup> Paxam 0.5 [AF]

**NITRAZEPAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*18.89	20.34	<sup>a</sup> Alodorm [AF]	<sup>a</sup> Mogadon [IL]

*Carboxamide derivatives***■ CARBAMAZEPINE****carbamazepine 100 mg/5 mL oral liquid, 300 mL**

5041H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	‡1	..	..	26.44	27.89	Tegretol Liquid [NV]	

**carbamazepine 100 mg tablet, 100**

5039F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	2	..	..	*23.89	25.34	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 4.58	*28.47	25.34	<sup>a</sup> Tegretol 100 [NV]	

**carbamazepine 200 mg tablet, 100**

1724R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	2	..	..	*30.89	31.60	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 4.60	*35.49	31.60	<sup>a</sup> Tegretol 200 [NV]	

**■ CARBAMAZEPINE**

**Note** Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 are equivalent for the purposes of substitution.

**carbamazepine 200 mg modified release tablet, 200**

5038E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	1	..	..	31.24	31.60	<sup>a</sup> Tegretol CR 200 [NV]	

**carbamazepine 200 mg modified release tablet, 100**

14671E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	2	..	..	*31.25	31.60	<sup>a</sup> Tegretol CR 200 [NV]	

**■ CARBAMAZEPINE**

**Note** Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 are equivalent for the purposes of substitution

**carbamazepine 400 mg modified release tablet, 200**

5037D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	1	..	..	47.24	31.60	<sup>a</sup> Tegretol CR 400 [NV]	

**carbamazepine 400 mg modified release tablet, 100**

14680P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(DP)</b>	2	..	..	*47.25	31.60	<sup>a</sup> Tegretol CR 400 [NV]	

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

2427R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>(NP)</b>	‡1	5	..	26.44	27.89	Tegretol Liquid [NV]	

**carbamazepine 100 mg tablet, 100**

2422L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*23.89	25.34	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 4.58	*28.47	25.34	<sup>a</sup> Tegretol 100 [NV]	

**carbamazepine 200 mg tablet, 100**

1706T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*30.89	31.60	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 4.60	*35.49	31.60	<sup>a</sup> Tegretol 200 [NV]	

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

14051M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*39.43	31.60	Tegretol Liquid [NV]	

**carbamazepine 100 mg tablet, 100**

14509P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	2	..	*34.31	31.60	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 9.16	*43.47	31.60	<sup>a</sup> Tegretol 100 [NV]	

**carbamazepine 200 mg tablet, 100**

14338P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	2	..	*48.31	31.60	<sup>a</sup> AVLOIRE [VQ]	<sup>a</sup> Carbamazepine Sandoz [NM]
			<sup>B</sup> 9.20	*57.51	31.60	<sup>a</sup> Tegretol 200 [NV]	

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 are equivalent for the purposes of substitution

**carbamazepine 400 mg modified release tablet, 200**

2431Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	47.24	31.60	<sup>a</sup> Tegretol CR 400 [NV]	

**carbamazepine 400 mg modified release tablet, 100**

14666X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*47.25	31.60	<sup>a</sup> Tegretol CR 400 [NV]	

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 are equivalent for the purposes of substitution.

**carbamazepine 200 mg modified release tablet, 200**

2426Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	31.24	31.60	<sup>a</sup> Tegretol CR 200 [NV]	

**carbamazepine 200 mg modified release tablet, 100**

14681Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*31.25	31.60	<sup>a</sup> Tegretol CR 200 [NV]	

**■ CARBAMAZEPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 are equivalent for the purposes of substitution

#### **Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **carbamazepine 400 mg modified release tablet, 200**

13918M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*81.03	31.60	<sup>a</sup> Tegretol CR 400 [NV]

#### **carbamazepine 400 mg modified release tablet, 100**

14662Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	2	..	*81.03	31.60	<sup>a</sup> Tegretol CR 400 [NV]

### ■ CARBAMAZEPINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 are equivalent for the purposes of substitution.

#### **Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **carbamazepine 200 mg modified release tablet, 200**

14050L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*49.03	31.60	<sup>a</sup> Tegretol CR 200 [NV]

#### **carbamazepine 200 mg modified release tablet, 100**

14673G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	2	..	*49.03	31.60	<sup>a</sup> Tegretol CR 200 [NV]

### ■ OXCARBAZEPINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

##### **5183**

Seizures

#### **Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### **oxcarbazepine 60 mg/mL oral liquid, 250 mL**

8588B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*99.91	31.60	Trileptal [NV]

#### **oxcarbazepine 150 mg tablet, 100**

8584T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.68	31.60	Trileptal [NV]

#### **oxcarbazepine 300 mg tablet, 100**

8585W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	84.79	31.60	Trileptal [NV]

#### **oxcarbazepine 600 mg tablet, 100**

8586X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	133.60	31.60	Trileptal [NV]

### ■ OXCARBAZEPINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**14932**

Seizures

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### **oxcarbazepine 60 mg/mL oral liquid, 250 mL**

13936L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*189.99	31.60	Trileptal [NV]

#### **oxcarbazepine 150 mg tablet, 100**

14562K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*99.91	31.60	Trileptal [NV]

#### **oxcarbazepine 300 mg tablet, 100**

14033N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*158.25	31.60	Trileptal [NV]

#### **oxcarbazepine 600 mg tablet, 100**

13935K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*258.73	31.60	Trileptal [NV]

#### **Fatty acid derivatives**

### ▪ TIAGABINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

#### **Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### **tiagabine 10 mg tablet, 50**

8222R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*111.25	31.60	Gabitril [TB]

#### **tiagabine 15 mg tablet, 50**

8223T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*156.13	31.60	Gabitril [TB]

#### **tiagabine 5 mg tablet, 50**

8221Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*62.35	31.60	Gabitril [TB]

### ▪ TIAGABINE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**14883**

Partial epileptic seizures

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### **tiagabine 10 mg tablet, 50**

13947C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*213.79	31.60	Gabitril [TB]

**tiagabine 15 mg tablet, 50**

13893F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*303.79	31.60	Gabitril [TB]

**tiagabine 5 mg tablet, 50**

13892E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*111.23	31.60	Gabitril [TB]

**■ VALPROATE**

**Caution** There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**valproate sodium 100 mg tablet, 100**

2294R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*35.71	31.60	Epilim [SW]

**valproate sodium 200 mg enteric tablet, 100**

2289L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*24.49	25.94	<sup>a</sup> APO-Sodium Valproate [TX] <sup>a</sup> Valprease 200 [RW]	<sup>a</sup> Sodium Valproate Sandoz [SZ] <sup>a</sup> Valproate Winthrop EC 200 [WA]
			<sup>B</sup> 1.86	*26.35	25.94	<sup>a</sup> Valpro EC 200 [AF] <sup>a</sup> Epilim EC [SW]	

**valproate sodium 500 mg enteric tablet, 100**

2290M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*34.87	31.60	<sup>a</sup> APO-Sodium Valproate [TX] <sup>a</sup> Valprease 500 [RW]	<sup>a</sup> Sodium Valproate Sandoz [SZ] <sup>a</sup> Valproate Winthrop EC 500 [WA]
			<sup>B</sup> 1.82	*36.69	31.60	<sup>a</sup> Valpro EC 500 [AF] <sup>a</sup> Epilim EC [SW]	

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

2293Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*42.29	31.60	Epilim Liquid [SW]

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

2295T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*42.29	31.60	Epilim Syrup [SW]

**■ VALPROATE**

**Caution** There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**valproate sodium 100 mg tablet, 100**

13840K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	2	..	*57.95	31.60	Epilim [SW]

**valproate sodium 200 mg enteric tablet, 100**

14017R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	2	..	*35.51	31.60	<sup>a</sup> APO-Sodium Valproate [TX] <sup>a</sup> Valprease 200 [RW]	<sup>a</sup> Sodium Valproate Sandoz [SZ] <sup>a</sup> Valproate Winthrop EC 200 [WA]
			<sup>B</sup> 3.72	*39.23	31.60	<sup>a</sup> Valpro EC 200 [AF] <sup>a</sup> Epilim EC [SW]	

**valproate sodium 500 mg enteric tablet, 100**

13917L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*56.27	31.60	<sup>a</sup> APO-Sodium Valproate [TX]	<sup>a</sup> Sodium Valproate Sandoz [SZ]



NP

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## ■ VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**4929**

Epileptic seizures

### Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

### vigabatrin 500 mg powder for oral liquid, 60 sachets

2668K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		
NP	1	5	..	61.21	31.60	Sabril [SW]		

### vigabatrin 500 mg tablet, 100

2667J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		
NP	1	5	..	87.22	31.60	Sabril [SW]		

## ■ VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**14903**

Epileptic seizures

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

### vigabatrin 500 mg powder for oral liquid, 60 sachets

13974L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		
NP	2	5	..	*108.97	31.60	Sabril [SW]		

### vigabatrin 500 mg tablet, 100

13919N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		
NP	2	5	..	*163.35	31.60	Sabril [SW]		

### Other antiepileptics

## ■ BRIVARACETAM

### Authority required (STREAMLINED)

**10210**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

### Treatment criteria:

- Must be treated by a neurologist.

### Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**

- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 100 mg tablet, 56**

11339T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

**brivaracetam 25 mg tablet, 56**

11328F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

**brivaracetam 50 mg tablet, 56**

11334M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

**brivaracetam 75 mg tablet, 56**

11356Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

■ **BRIVARACETAM****Authority required (STREAMLINED)****10251**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

11349H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	194.50	31.60	Briviact [UC]

■ **BRIVARACETAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****10208**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 100 mg tablet, 56**

11357R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

NP

**brivaracetam 25 mg tablet, 56**

11327E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

NP

**brivaracetam 50 mg tablet, 56**

11338R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

NP

**brivaracetam 75 mg tablet, 56**

11350J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	157.29	31.60	Briviact [UC]

NP

## ■ BRIVARACETAM

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

10330

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

### Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

### brivaracetam 10 mg/mL oral liquid, 300 mL

11358T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	194.50	31.60	Briviact [UC]

## ■ CANNABIDIOL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Severe myoclonic epilepsy in infancy (Dravet syndrome)

### Clinical criteria:

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

### Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

### cannabidiol 100 mg/mL oral liquid, 100 mL

12467E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1535.31	31.60	Epidyolex [JA]

## ■ CANNABIDIOL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required

Seizures of the Lennox-Gastaut syndrome

### Clinical criteria:

- Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible), **AND**
- Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures, **AND**
- Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

### Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; OR
  - Must be treated by a neurologist if treatment is being continued or re-initiated; OR
  - Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
  - Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.
- Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**cannabidiol 100 mg/mL oral liquid, 100 mL**

13277T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1535.31	31.60	Epidyolex [JA]

**■ GABAPENTIN****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**gabapentin 100 mg capsule, 100**

8505P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.63	19.08	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> GABAPENTIN [RF] <sup>a</sup> Nupentin 100 [AF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Neurontin [UJ]

**gabapentin 300 mg capsule, 100**

1834M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.10	24.55	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> GABAPENTIN [RF] <sup>a</sup> Nupentin 300 [AF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> GABAPENTIN-WGR [WG] <sup>a</sup> Neurontin [UJ]

**gabapentin 400 mg capsule, 100**

1835N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.61	28.06	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> GABAPENTIN [RF] <sup>a</sup> Nupentin 400 [AF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> GABAPENTIN-WGR [WG] <sup>a</sup> Neurontin [UJ]

**gabapentin 600 mg tablet, 100**

8559L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.06	31.60	<sup>a</sup> APX-GABAPENTIN [TX] <sup>a</sup> GABAPENTIN [RF] <sup>a</sup> Pharmacor Gabapentin 600 [CR]	<sup>a</sup> Gabapentin APOTEX [TY] <sup>a</sup> Neurontin [UJ]

**gabapentin 800 mg tablet, 100**

8389M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.29	31.60	<sup>a</sup> Gabapentin APOTEX [TY] <sup>a</sup> Neurontin [UJ]	<sup>a</sup> GABAPENTIN [RF] <sup>a</sup> Pharmacor Gabapentin 800 [CR]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****8813**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 50 mg tablet, 14**

9333F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.36	23.81	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 100 mg tablet, 14**

9334G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	31.28	31.60	<sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]	<sup>a</sup> Vimcosa [CR]

**lacosamide 150 mg tablet, 14**

9336J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	40.18	31.60	<sup>a</sup> Vimcosa [CR]	<sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****14857**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 100 mg tablet, 56**

13867W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*158.11	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 50 mg tablet, 14**

14011K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*84.67	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 50 mg tablet, 14**

10293R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*49.07	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****12225**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Dose titration at the start of therapy, during therapy or to gradually cease treatment

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 100 mg tablet, 14**

12633X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	31.28	31.60	<sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]	<sup>a</sup> Vimcosa [CR]

**lacosamide 150 mg tablet, 14**

12649R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	40.18	31.60	<sup>a</sup> Vimcosa [CR]	<sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****8770**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Authority required (STREAMLINED)****8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 100 mg tablet, 56**

9335H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	84.72	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****14857**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 150 mg tablet, 56**

14053P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*232.89	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 200 mg tablet, 56**

13951G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*307.71	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 10 mg/mL oral liquid, 200 mL**

14048J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡12	5	..	*708.99	31.60	Vimpat [UC]

## ■ LACOSAMIDE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**15070**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

### Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

### Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

### lacosamide 10 mg/mL oral liquid, 200 mL

12628P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*125.23	31.60	Vimpat [UC]

## ■ LACOSAMIDE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

**15089**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

### Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

### lacosamide 10 mg/mL oral liquid, 200 mL

14013M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±4	5	..	*241.99	31.60	Vimpat [UC]

## ■ LACOSAMIDE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

### Authority required (STREAMLINED)

**8770**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

### Treatment criteria:

- Must be treated by a neurologist.

### Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Authority required (STREAMLINED)****8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 150 mg tablet, 56**

9337K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	120.67	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 200 mg tablet, 56**

9338L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	158.09	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 10 mg/mL oral liquid, 200 mL**

11694L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±6	5	..	*358.77	31.60	Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15089**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

**lacosamide 100 mg tablet, 56**

13839J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*158.11	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 150 mg tablet, 56**

13838H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*232.89	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 200 mg tablet, 56**

13949E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*307.71	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]



**lacosamide 50 mg tablet, 14**

14049K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*84.67	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**■ LACOSAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15070**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician; OR
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.

**lacosamide 100 mg tablet, 56**

12634Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	84.72	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 150 mg tablet, 56**

12627N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	120.67	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 200 mg tablet, 56**

12658F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	158.09	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**lacosamide 50 mg tablet, 14**

12626M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*49.07	31.60	<sup>a</sup> Lacosam [AF] <sup>a</sup> Lacosamide Lupin [GQ] <sup>a</sup> Vimcosa [CR]	<sup>a</sup> Lacosamide ARX [XT] <sup>a</sup> Lacosamide Sandoz [SZ] <sup>a</sup> Vimpat [UC]

**■ LAMOTRIGINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****11081**

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

**lamotrigine 100 mg tablet, 56**

2850B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.28	24.73	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 100 [ZS]

			<sup>B</sup> 3.45	26.73	24.73	<sup>a</sup> Lamictal [AS]	
<b>lamotrigine 200 mg tablet, 56</b>							
2851C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.96	31.41	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 200 [ZS]
			<sup>B</sup> 3.46	33.42	31.41	<sup>a</sup> Lamictal [AS]	
<b>lamotrigine 25 mg tablet, 56</b>							
2848X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 25 [ZS]
			<sup>B</sup> 4.28	22.04	19.21	<sup>a</sup> Lamictal [AS]	
<b>lamotrigine 5 mg tablet, 56</b>							
8063J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.61	20.06	Lamictal [AS]	
<b>lamotrigine 50 mg tablet, 56</b>							
2849Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.35	20.80	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 50 [ZS]
			<sup>B</sup> 3.44	22.79	20.80	<sup>a</sup> Lamictal [AS]	

## ■ LAMOTRIGINE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**14855**

Epileptic seizures

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

### lamotrigine 100 mg tablet, 56

14052N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*33.11	31.60	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 100 [ZS]
			<sup>B</sup> 6.90	*40.01	31.60	<sup>a</sup> Lamictal [AS]	

### lamotrigine 200 mg tablet, 56

13843N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*46.47	31.60	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 200 [ZS]
			<sup>B</sup> 6.92	*53.39	31.60	<sup>a</sup> Lamictal [AS]	

### lamotrigine 25 mg tablet, 56

13842M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 25 [ZS]
			<sup>B</sup> 8.56	*30.63	23.52	<sup>a</sup> Lamictal [AS]	

### lamotrigine 5 mg tablet, 56

14047H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*23.77	25.22	Lamictal [AS]	

**lamotrigine 50 mg tablet, 56**

13975M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.25	26.70	<sup>a</sup> APX-Lamotrigine [TY] <sup>a</sup> Lamotrigine GH [GQ] <sup>a</sup> Logem [AL] <sup>a</sup> Sandoz Lamotrigine [HX]	<sup>a</sup> LAMITAN [RF] <sup>a</sup> LAMOTRIGINE-WGR [WG] <sup>a</sup> Reedos 50 [ZS]
			<sup>B</sup> 6.88	*32.13	26.70	<sup>a</sup> Lamictal [AS]	

**■ LEVETIRACETAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****11116**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**levetiracetam 1 g tablet, 60**

8656N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.16	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 1000 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> Levetiracetam Viatris [MQ] <sup>a</sup> Levi 1000 [RW]

**levetiracetam 250 mg tablet, 60**

8654L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.08	24.53	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 250 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> Levetiracetam Viatris [MQ] <sup>a</sup> Levi 250 [RW]

**levetiracetam 500 mg tablet, 60**

8655M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.49	30.94	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 500 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> Levi 500 [RW]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]

**■ LEVETIRACETAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****11077**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

9169N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	78.10	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron [ZS] <sup>a</sup> Levetiracetam GH [GQ]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levetiracetam-AFT [AE]

## ■ LEVETIRACETAM

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**14964**

Partial epileptic seizures

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

### levetiracetam 1 g tablet, 60

13937M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*68.87	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 1000 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> Levetiracetam Viatris [MQ] <sup>a</sup> Levi 1000 [RW]

### levetiracetam 250 mg tablet, 60

13992K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*32.71	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 250 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> Levetiracetam Viatris [MQ] <sup>a</sup> Levi 250 [RW]

### levetiracetam 500 mg tablet, 60

14034P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*45.53	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kevtam 500 [AF] <sup>a</sup> Levetiracetam GH [GQ] <sup>a</sup> Levetiracetam SZ [SZ] <sup>a</sup> Levi 500 [RW]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levactam [ZS] <sup>a</sup> Levetiracetam Mylan [AL] <sup>a</sup> LEVETIRACETAM-WGR [WG] <sup>a</sup> NOUMED LEVETIRACETAM [VO]

## ■ LEVETIRACETAM

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**14988**

Partial epileptic seizures

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

### levetiracetam 100 mg/mL oral liquid, 300 mL

13993L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*144.21	31.60	<sup>a</sup> APO-Levetiracetam [TX] <sup>a</sup> Kerron [ZS] <sup>a</sup> Levetiracetam GH [GQ]	<sup>a</sup> Keppra [UC] <sup>a</sup> Levetiracetam-AFT [AE]

## ■ PERAMPANEL

### Authority required (STREAMLINED)

**4656**

Intractable partial epileptic seizures

Treatment Phase: Initial

**Clinical criteria:**

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Treatment criteria:**

- Must be treated by a neurologist.

**perampanel 2 mg tablet, 7**

10157N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*46.85	31.60	Fycompa [EI]

▪ **PERAMPANEL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4658**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 12 mg tablet, 28**

10159Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	288.87	31.60	Fycompa [EI]

**perampanel 4 mg tablet, 28**

10162W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	148.68	31.60	Fycompa [EI]

**perampanel 6 mg tablet, 28**

10163X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	218.79	31.60	Fycompa [EI]

**perampanel 8 mg tablet, 28**

10160R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	288.87	31.60	Fycompa [EI]

**perampanel 10 mg tablet, 28**

10151G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	288.87	31.60	Fycompa [EI]

▪ **PERAMPANEL**

**Note** No applications for increased maximum quantities will be authorised.

**Authority required (STREAMLINED)**

**7815**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, **AND**
- The treatment must be for dose titration purposes.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 2 mg tablet, 7**

11436X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*46.85	31.60	Fycompa [EI]

▪ **PERAMPANEL**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14852**

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 12 mg tablet, 28**

13865R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

**perampanel 4 mg tablet, 28**

13948D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*288.89	31.60	Fycompa [EI]

**perampanel 6 mg tablet, 28**

14010J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*429.11	31.60	Fycompa [EI]

**perampanel 8 mg tablet, 28**

13970G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

**perampanel 10 mg tablet, 28**

13914H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

■ **PERAMPANEL**

**Note** No applications for increased maximum quantities will be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**7789**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 12 mg tablet, 28**

11409L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	288.87	31.60	Fycompa [EI]

**perampanel 4 mg tablet, 28**

11418Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	148.68	31.60	Fycompa [EI]

**perampanel 6 mg tablet, 28**

11407J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	218.79	31.60	Fycompa [EI]

**perampanel 8 mg tablet, 28**

11429M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	288.87	31.60	Fycompa [EI]

**perampanel 10 mg tablet, 28**

11428L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	288.87	31.60	Fycompa [EI]

## ■ PERAMPANEL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14847**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

### perampanel 4 mg tablet, 28

13864Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*288.89	31.60	Fycompa [EI]

### perampanel 6 mg tablet, 28

14046G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*429.11	31.60	Fycompa [EI]

## ■ PERAMPANEL

**Note** No applications for increased maximum quantities will be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14847**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

### perampanel 12 mg tablet, 28

14012L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

### perampanel 8 mg tablet, 28

13915J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

### perampanel 10 mg tablet, 28

13971H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*569.29	31.60	Fycompa [EI]

## ■ STIRIPENTOL

**Authority required (STREAMLINED)**

**11642**

Severe myoclonic epilepsy in infancy (Dravet syndrome)

**Clinical criteria:**

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs, **AND**
- The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR

- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

**stiripentol 250 mg capsule, 60**

12103B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*670.03	31.60	Diacomit [EU]

**stiripentol 250 mg powder for oral liquid, 60 sachets**

12106E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*670.03	31.60	Diacomit [EU]

**stiripentol 500 mg capsule, 60**

12107F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1295.91	31.60	Diacomit [EU]

**stiripentol 500 mg powder for oral liquid, 60 sachets**

12088F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1295.91	31.60	Diacomit [EU]

**■ SULTHIAME**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**sulthiame 200 mg tablet, 200**

2100M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	163.32	31.60	Ospolot [FF]

**sulthiame 50 mg tablet, 200**

2099L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	69.62	31.60	Ospolot [FF]

**■ SULTHIAME**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sulthiame 200 mg tablet, 200**

14016Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*318.19	31.60	Ospolot [FF]

**sulthiame 50 mg tablet, 200**

13916K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*126.39	31.60	Ospolot [FF]

**■ TOPIRAMATE**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5516**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**topiramate 200 mg tablet, 60**

8166T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	31.03	31.60	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 200 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]



## ■ TOPIRAMATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**5173**

Seizures

#### Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

### topiramate 15 mg capsule, 60

8371N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	24.77	26.22	Topamax Sprinkle [JC]

### topiramate 25 mg capsule, 60

8372P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	22.77	24.22	Topamax Sprinkle [JC]

### topiramate 50 mg capsule, 60

8520K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	28.99	30.44	Topamax Sprinkle [JC]

## ■ TOPIRAMATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**14931**

Seizures

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

### topiramate 15 mg capsule, 60

14063E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*36.09	31.60	Topamax Sprinkle [JC]

### topiramate 25 mg capsule, 60

13905W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*32.09	31.60	Topamax Sprinkle [JC]

### topiramate 50 mg capsule, 60

13878K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*44.53	31.60	Topamax Sprinkle [JC]

## ■ TOPIRAMATE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**14973**

Seizures

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**topiramate 200 mg tablet, 60**

14009H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*48.61	31.60	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 200 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**■ TOPIRAMATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****5516**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)****5325**

Migraine

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 100 mg tablet, 60**

8165R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	23.91	25.36	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 100 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**topiramate 25 mg tablet, 60**

8163P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 25 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**topiramate 50 mg tablet, 60**

8164Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.10	21.55	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 50 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**■ TOPIRAMATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****14973**

Seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)****14901**

Migraine

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 100 mg tablet, 60**

14008G

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*34.37	31.60	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 100 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**topiramate 25 mg tablet, 60**

13969F

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*22.07	23.52	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 25 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**topiramate 50 mg tablet, 60**

13913G

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*26.75	28.20	<sup>a</sup> APO-Topiramate [TX] <sup>a</sup> RBX Topiramate [RA] <sup>a</sup> Topiramate Sandoz [SZ]	<sup>a</sup> Epiramax 50 [RW] <sup>a</sup> Tamate [AF] <sup>a</sup> TOPIRAMATE-WGR [WG]

**■ ZONISAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**zonisamide 100 mg capsule, 56**

9390F

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*75.69	31.60	Zonegran [GH]

**zonisamide 25 mg capsule, 56**

9388D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	24.65	26.10	Zonegran [GH]

**zonisamide 50 mg capsule, 56**

9389E

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	32.13	31.60	Zonegran [GH]

**■ ZONISAMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**14883**

Partial epileptic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**zonisamide 100 mg capsule, 56**

13854E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*139.11	31.60	Zonegran [GH]

**zonisamide 25 mg capsule, 56**

13853D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*35.85	31.60	Zonegran [GH]

**zonisamide 50 mg capsule, 56**

13988F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*50.81	31.60	Zonegran [GH]

**ANTI-PARKINSON DRUGS****ANTICHOLINERGIC AGENTS***Tertiary amines***TRIHENXYPHENIDYL (BENZHEXOL)****trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200**

1109J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	18.67	20.12	Artane [RW]

**trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200**

1110K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	22.37	23.82	Artane [RW]

*Ethers of tropine or tropine derivatives***BENZATROPINE****benzatropine mesilate 2 mg tablet, 60**

2362H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	18.32	19.77	Benztrop [FF]

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

11249C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	118.61	31.60	Benzatropine Injection [FF]

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

11255J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	118.61	31.60	Benzatropine Injection [FF]

**DOPAMINERGIC AGENTS***Dopa and dopa derivatives***LEVODOPA + BENSERAZIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 200 mg + benserazide 50 mg tablet, 100**

2228G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	39.49	31.60	Madopar [RO]

**levodopa 100 mg + benserazide 25 mg capsule, 100**

2225D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.53	30.98	Madopar 125 [RO]

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

2231K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	33.09	31.60	Madopar HBS [RO]

**levodopa 200 mg + benserazide 50 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2226E	1	5	..	39.49	31.60	Madopar [RO]

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2227F	1	5	..	25.17	26.62	Madopar 62.5 [RO]

**levodopa 100 mg + benserazide 25 mg dispersible tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8219N	1	5	..	35.27	31.60	Madopar Rapid 125 [RO]

**levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8218M	1	5	..	25.17	26.62	Madopar Rapid 62.5 [RO]

**levodopa 100 mg + benserazide 25 mg tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2229H	1	5	..	29.53	30.98	Madopar 125 [RO]

**■ LEVODOPA + BENSERAZIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**levodopa 200 mg + benserazide 50 mg tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14428J	2	5	..	*65.53	31.60	Madopar [RO]

**levodopa 100 mg + benserazide 25 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14387F	2	5	..	*45.61	31.60	Madopar 125 [RO]

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14525L	2	5	..	*52.73	31.60	Madopar HBS [RO]

**levodopa 200 mg + benserazide 50 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14551W	2	5	..	*65.53	31.60	Madopar [RO]

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14388G	2	5	..	*36.89	31.60	Madopar 62.5 [RO]

**levodopa 100 mg + benserazide 25 mg dispersible tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14552X	2	5	..	*57.09	31.60	Madopar Rapid 125 [RO]

**levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14356N	2	5	..	*36.89	31.60	Madopar Rapid 62.5 [RO]

**levodopa 100 mg + benserazide 25 mg tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14455T	2	5	..	*45.61	31.60	Madopar 125 [RO]

**■ LEVODOPA + CARBIDOPA****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 100 mg + carbidopa 25 mg tablet, 100**

1242J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	32.44	31.60	<sup>a</sup> APO-Levodopa/Carbidopa [TX] <sup>a</sup> SINADOPA 100/25 [RW]	<sup>a</sup> Kinson [AF] <sup>a</sup> Sinemet 100/25 [AL]

**levodopa 250 mg + carbidopa 25 mg tablet, 100**

1245M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	36.87	31.60	<sup>a</sup> APO-Levodopa/Carbidopa [TX] <sup>a</sup> Sinemet [AL]	<sup>a</sup> SINADOPA 250/25 [RW]

**▪ LEVODOPA + CARBIDOPA****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**levodopa 200 mg + carbidopa 50 mg modified release tablet, 100**

1255C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	69.32	31.60	Sinemet CR [AL]

**▪ LEVODOPA + CARBIDOPA****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**levodopa 200 mg + carbidopa 50 mg modified release tablet, 100**

14322T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*125.77	31.60	Sinemet CR [AL]

**▪ LEVODOPA + CARBIDOPA****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**levodopa 100 mg + carbidopa 25 mg tablet, 100**

14427H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*51.43	31.60	<sup>a</sup> APO-Levodopa/Carbidopa [TX] <sup>a</sup> SINADOPA 100/25 [RW]	<sup>a</sup> Kinson [AF] <sup>a</sup> Sinemet 100/25 [AL]

**levodopa 250 mg + carbidopa 25 mg tablet, 100**

14454R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*60.29	31.60	<sup>a</sup> APO-Levodopa/Carbidopa [TX] <sup>a</sup> Sinemet [AL]	<sup>a</sup> SINADOPA 250/25 [RW]

**▪ LEVODOPA + CARBIDOPA**

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10197**

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

11919H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	4	5	..	*5903.55	31.60	Duodopa [VE]	

**■ LEVODOPA + CARBIDOPA**

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****10386**

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

8970D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	8	5	..	*11698.59	31.60	Duodopa [VE]	

**■ LEVODOPA + CARBIDOPA + ENTACAPONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100**

8798C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*137.07	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 100/25/200mg [SZ]

**levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100**

9345W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*141.95	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 125/31.25/200mg [SZ]

**levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100**

8799D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*149.25	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 150/37.5/200mg [SZ]

**levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100**

9292C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*160.43	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 200/50/200mg [SZ]

**levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100**

8797B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*124.91	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 50/12.5/200mg [SZ]

**levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100**

9344T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	4	..	*130.27	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 75/18.75/200mg [SZ]

■ **LEVODOPA + CARBIDOPA + ENTACAPONE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100**

14554B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*265.67	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 100/25/200mg [SZ]

**levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100**

14527N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*275.47	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 125/31.25/200mg [SZ]

**levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100**

14357P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*290.03	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 150/37.5/200mg [SZ]

**levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100**

14457X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*312.43	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 200/50/200mg [SZ]

**levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100**

14456W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*241.35	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 50/12.5/200mg [SZ]

**levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100**

14498C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*252.07	31.60	<sup>a</sup> Carlevent [TX] <sup>a</sup> LECTEVA [TB]	<sup>a</sup> L.C.E. Sandoz [HX] <sup>a</sup> Stalevo 75/18.75/200mg [SZ]

*Adamantane derivatives*■ **AMANTADINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must not be drug induced.

**amantadine hydrochloride 100 mg capsule, 100**

3016R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.56	31.60	<sup>a</sup> AMANTAMED [DZ]	<sup>a</sup> Symmetrel 100 [NV]

■ **AMANTADINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**



Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be drug induced.

**amantadine hydrochloride 100 mg capsule, 100**

12486K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*55.67	31.60	<sup>a</sup> AMANTAMED [DZ]	<sup>a</sup> Symmetrel 100 [NV]

**Dopamine agonists****■ APOMORPHINE****Authority required (STREAMLINED)****10844**

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

12306Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	36	5	..	*6165.03	31.60	Movapo [TD]

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

12142C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	18	5	..	*7562.73	31.60	Apomine Solution for Infusion [IT]

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

12319J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	36	5	..	*8152.59	31.60	Movapo PFS [TD]

**■ APOMORPHINE****Authority required (STREAMLINED)****15542**

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

14407G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	72	5	..	*12222.03	31.60	Movapo [TD]

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

14375N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	36	5	..	*15017.07	31.60	Apomine Solution for Infusion [IT]

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

14377Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	72	5	..	*16197.15	31.60	Movapo PFS [TD]

**■ APOMORPHINE**

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****10844**

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

12133N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	20	5	..	*2723.47	31.60	<sup>a</sup> Apomine Intermittent [IT]

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

12137T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	20	5	..	*2723.47	31.60	<sup>a</sup> Movapo Pen [TD]

**■ APOMORPHINE**

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINED)****15542**

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

14309D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	40	5	..	*5338.27	31.60	<sup>a</sup> Apomine Intermittent [IT]

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

14485J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	40	5	..	*5338.27	31.60	<sup>a</sup> Movapo Pen [TD]

**■ BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson disease

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*32.73	31.60	Parlodel [SZ]

**■ BROMOCRIPTINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

Acromegaly

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**bromocriptine 2.5 mg tablet, 30**

13979R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*51.99	31.60	Parlodel [SZ]

▪ **CABERGOLINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**cabergoline 1 mg tablet, 30**

8393R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	49.93	31.60	Cabaser [PF]

NP

**cabergoline 2 mg tablet, 30**

8394T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.34	31.60	Cabaser [PF]

NP

▪ **CABERGOLINE**

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**cabergoline 1 mg tablet, 30**

14516B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*86.41	31.60	Cabaser [PF]

NP

**cabergoline 2 mg tablet, 30**

14543K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	2	5	..	*111.23	31.60	Cabaser [PF]	

**■ PRAMIPEXOLE**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**pramipexole dihydrochloride monohydrate 1 mg tablet, 100**

9153R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	77.97	31.60	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simipex 1 [RW]	<sup>a</sup> Sifrol [BY] <sup>a</sup> Simpral [AF]

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

9151P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	16.91	18.36	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simpral [AF]	<sup>a</sup> Simipex 0.125 [RW]
			<sup>B</sup> 3.58	20.49	18.36	<sup>a</sup> Sifrol [BY]	

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

9152Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	28.24	29.69	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simpral [AF]	<sup>a</sup> Simipex 0.25 [RW]
			<sup>B</sup> 3.77	32.01	29.69	<sup>a</sup> Sifrol [BY]	

**■ PRAMIPEXOLE**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pramipexole dihydrochloride monohydrate 1 mg tablet, 100**

14532W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*143.93	31.60	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simipex 1 [RW]	<sup>a</sup> Sifrol [BY] <sup>a</sup> Simpral [AF]

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

14329E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*43.03	31.60	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simpral [AF]	<sup>a</sup> Simipex 0.25 [RW]
			<sup>B</sup> 7.54	*50.57	31.60	<sup>a</sup> Sifrol [BY]	

**■ PRAMIPEXOLE**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3418X	1	5	..	21.22	22.67	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3419Y	1	5	..	28.73	30.18	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3420B	1	5	..	44.00	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5143Q	1	5	..	59.26	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3421C	1	5	..	80.09	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5145T	1	5	..	95.35	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3422D	1	5	..	113.40	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

**■ PRAMIPEXOLE**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

- (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9393J	1	2	..	16.91	18.36	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simpral [AF]	<sup>a</sup> Simipex 0.125 [RW]
			<sup>b</sup> 3.58	20.49	18.36	<sup>a</sup> Sifrol [BY]	

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9394K	1	2	..	28.24	29.69	<sup>a</sup> APO-Pramipexole [TX] <sup>a</sup> Simpral [AF]	<sup>a</sup> Simipex 0.25 [RW]
			<sup>b</sup> 3.77	32.01	29.69	<sup>a</sup> Sifrol [BY]	

## ■ PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30

14324X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.99	30.44	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30

14459B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*44.01	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30

14360T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*74.55	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30

14556D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*105.07	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30

14460C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*148.39	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30

14461D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*180.43	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

### pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30

14325Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*218.33	31.60	<sup>a</sup> APO-Pramipexole ER [TX] <sup>a</sup> SIMIPEX XR [RW]	<sup>a</sup> Sifrol ER [BY]

## ■ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### rotigotine 8 mg/24 hours patch, 28

11140H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	111.23	31.60	Neupro [UC]

### rotigotine 4 mg/24 hours patch, 28

2384L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	90.95	31.60	Neupro [UC]

### rotigotine 6 mg/24 hours patch, 28

2410W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	101.39	31.60	Neupro [UC]

## ■ ROTIGOTINE

**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 2 mg/24 hours patch, 28**

2385M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	71.59	31.60	Neupro [UC]

**■ ROTIGOTINE****Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 8 mg/24 hours patch, 28**

14359R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*213.77	31.60	Neupro [UC]

**rotigotine 4 mg/24 hours patch, 28**

14326B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*171.19	31.60	Neupro [UC]

**rotigotine 6 mg/24 hours patch, 28**

14431M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*193.11	31.60	Neupro [UC]

**■ ROTIGOTINE****Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**rotigotine 2 mg/24 hours patch, 28**

14327C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*130.53	31.60	Neupro [UC]

**Monoamine oxidase B inhibitors****■ RASAGILINE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Parkinson disease

**rasagiline 1 mg tablet, 30**

1952R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.53	31.60	<sup>a</sup> Alziras [RW]	<sup>a</sup> Pharmacor Rasagiline [CR]
						<sup>a</sup> Rasagiline Lupin [HQ]	<sup>a</sup> Rasagiline Sandoz [SZ]
						<sup>a</sup> Rasagiline-Teva [EV]	<sup>a</sup> RASAGILINE-WGR [WG]
						<sup>a</sup> Azilect [TB]	
			<sup>b</sup> 2.56	36.09	31.60		

**■ RASAGILINE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**rasagiline 1 mg tablet, 30**

14458Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*53.61	31.60	<sup>a</sup> Alziras [RW]	<sup>a</sup> Pharmacor Rasagiline [CR]
						<sup>a</sup> Rasagiline Lupin [HQ]	<sup>a</sup> Rasagiline Sandoz [SZ]
						<sup>a</sup> Rasagiline-Teva [EV]	<sup>a</sup> RASAGILINE-WGR [WG]
						<sup>a</sup> Azilect [TB]	
			<sup>b</sup> 5.12	*58.73	31.60		

## ■ SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Parkinson disease

### **Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### safinamide 50 mg tablet, 30

11656L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	63.20	31.60	Xadago [IX]

### safinamide 100 mg tablet, 30

11666B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	112.93	31.60	Xadago [IX]

## ■ SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Parkinson disease

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### safinamide 50 mg tablet, 30

14391K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*112.95	31.60	Xadago [IX]

### safinamide 100 mg tablet, 30

14528P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*217.35	31.60	Xadago [IX]

## ■ SELEGILINE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Late stage Parkinson disease

### **Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### selegiline hydrochloride 5 mg tablet, 100

1973W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	53.77	31.60	Eldepryl [OX]

## ■ SELEGILINE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Late stage Parkinson disease

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### selegiline hydrochloride 5 mg tablet, 100

14430L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	2	5	..	*94.09	31.60	Eldepryl [OX]

*Other dopaminergic agents*



## ■ ENTACAPONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Parkinson disease

### Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

### entacapone 200 mg tablet, 100

8367J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*179.23	31.60	Comtan [SZ]

## ■ ENTACAPONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Parkinson disease

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

### entacapone 200 mg tablet, 100

14542J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	4	..	*349.99	31.60	Comtan [SZ]

## ■ OPICAPONE

### Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Parkinson disease

### Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

### opicapone 50 mg capsule, 30

13206C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	151.69	31.60	Ongentys [XY]

## ■ PSYCHOLEPTICS

### ANTIPSYCHOTICS

*Phenothiazines with aliphatic side-chain*

## ■ CHLORPROMAZINE

### Restricted benefit

For prescribing by certain health practitioners

### Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

1195X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	34.45	31.60	Largactil [IX]

### chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL

1201F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	24.91	26.36	Largactil [IX]

**chlorpromazine hydrochloride 100 mg tablet, 100**

1199D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.55	30.00	Largactil [IX]

**chlorpromazine hydrochloride 25 mg tablet, 100**

1197B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.45	19.90	Largactil [IX]

*Phenothiazines with piperidine structure***■ PERICIAZINE****Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**periciazine 10 mg tablet, 100**

3053Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.41	23.86	Neulactil [IX]

**periciazine 2.5 mg tablet, 100**

3052P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.43	19.88	Neulactil [IX]

*Butyrophenone derivatives***■ HALOPERIDOL****haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

2768Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.66	26.11	Serenace [AS]

**haloperidol 2 mg/mL oral liquid, 100 mL**

2763K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	23.98	25.43	Serenace [AS]

**haloperidol 1.5 mg tablet, 100**

2767P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.28	18.73	Serenace [AS]

**haloperidol 5 mg tablet, 50**

2770T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.14	18.59	Serenace [AS]

**haloperidol 500 microgram tablet, 100**

2761H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.93	18.38	Serenace [AS]

**■ HALOPERIDOL DECANOATE****haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules**

2766N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.45	31.60	Haldol decanoate [IX]

**haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules**

2765M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.91	31.36	Haldol decanoate [IX]

*Indole derivatives***■ LURASIDONE****Authority required (STREAMLINED)****4246**

Schizophrenia

**lurasidone hydrochloride 80 mg tablet, 30**

10529E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.68	31.60	<sup>a</sup> APO-Lurasidone [TX] <sup>a</sup> Lavione [AF] <sup>a</sup> Lurasidone Sandoz [SZ]	<sup>a</sup> Latuda [SE] <sup>a</sup> Lurasidone Lupin [GQ] <sup>a</sup> LURASIDONE SUN [RA]

<sup>a</sup> LURASIDONE-WGR [WG] <sup>a</sup> Pharmacor Lurasidone [CR]

**lurasidone hydrochloride 40 mg tablet, 30**

10526B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.07	30.52	<sup>a</sup> APO-Lurasidone [TX] <sup>a</sup> Lavione [AF] <sup>a</sup> Lurasidone Sandoz [SZ] <sup>a</sup> LURASIDONE-WGR [WG]	<sup>a</sup> Latuda [SE] <sup>a</sup> Lurasidone Lupin [GQ] <sup>a</sup> LURASIDONE SUN [RA] <sup>a</sup> Pharmacor Lurasidone [CR]

**■ ZIPRASIDONE****Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5742**

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**ziprasidone 20 mg capsule, 60**

9070J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	43.04	31.60	<sup>a</sup> Zeldox [UJ] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Ziprasidone GH [GQ]

**ziprasidone 40 mg capsule, 60**

9071K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	72.73	31.60	<sup>a</sup> Zeldox [UJ] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Ziprasidone GH [GQ]

**ziprasidone 60 mg capsule, 60**

9072L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	102.02	31.60	<sup>a</sup> Zeldox [UJ] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Ziprasidone GH [GQ]

**ziprasidone 80 mg capsule, 60**

9073M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	132.62	31.60	<sup>a</sup> Zeldox [UJ] <sup>a</sup> ZIPROX [RW]	<sup>a</sup> Ziprasidone GH [GQ]

**Thioxanthene derivatives****■ FLUPENTIXOL DECANOATE****flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules**

2257T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	50.81	31.60	Fluanxol Concentrated Depot [LU]

**flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules**

2255Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	25.71	27.16	Fluanxol Depot [LU]

**■ ZUCLOPENTHIXOL DECANOATE****Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules**

8097E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	31.56	31.60	Clopixol Depot [LU]

**Diazepines, oxazepines, thiazepines and oxepines****■ ASENAPINE****Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)**

**5773**

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)****5719**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

**asenapine 10 mg sublingual wafer, 60**

5141N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	224.79	31.60	Saphris [OQ]

**asenapine 5 mg sublingual wafer, 60**

5140M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	138.23	31.60	Saphris [OQ]

**■ OLANZAPINE****Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 2.5 mg tablet, 28**

8170B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.95	18.40	<sup>a</sup> APO-OLANZAPINE [TX] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 2.5 [ZS] <sup>a</sup> Zypine [AF]	<sup>a</sup> Olanzapine APOTEX [GX] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]
			<sup>B</sup> 7.83	24.78	18.40	<sup>a</sup> Zyprexa [PB]	

**olanzapine 5 mg tablet, 28**

8185T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	<sup>a</sup> APO-OLANZAPINE [TX] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 5 [ZS] <sup>a</sup> Zypine [AF]	<sup>a</sup> Olanzapine APOTEX [GX] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]
			<sup>B</sup> 10.17	28.04	19.32	<sup>a</sup> Zyprexa [PB]	

**olanzapine 7.5 mg tablet, 28**

8186W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.63	20.08	<sup>a</sup> APO-OLANZAPINE [TX] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]	<sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 7.5 [ZS] <sup>a</sup> Zypine [AF]
			<sup>B</sup> 4.87	23.50	20.08	<sup>a</sup> Zyprexa [PB]	

**olanzapine 10 mg tablet, 28**

8187X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.28	21.73	<sup>a</sup> APO-OLANZAPINE [TX] <sup>a</sup> Olanzapine RBX [RA] <sup>a</sup> Ozin 10 [ZS] <sup>a</sup> Zypine [AF]	<sup>a</sup> Olanzapine APOTEX [GX] <sup>a</sup> Olanzapine Sandoz [SZ] <sup>a</sup> PRYZEX [RW]
			<sup>B</sup> 4.92	25.20	21.73	<sup>a</sup> Zyprexa [PB]	

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 5 mg orally disintegrating tablet, 28**

3381Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> OLANZAPINE ODT-WGR [WG]
						<sup>a</sup> Olanzapine Sandoz ODT 5 [SZ]	<sup>a</sup> PRYZEX ODT [RW]
						<sup>a</sup> Zypine ODT [AF]	

**olanzapine 5 mg wafer, 28**

8433W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 10.17	28.04	19.32	<sup>a</sup> Zyprexa Zydis [PB]

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 10 mg orally disintegrating tablet, 28**

3382B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.28	21.73	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> OLANZAPINE ODT-WGR [WG]
						<sup>a</sup> Olanzapine Sandoz ODT 10 [SZ]	<sup>a</sup> PRYZEX ODT [RW]
						<sup>a</sup> Zypine ODT [AF]	

**olanzapine 10 mg wafer, 28**

8434X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 9.95	30.23	21.73	<sup>a</sup> Zyprexa Zydis [PB]

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 15 mg orally disintegrating tablet, 28**

3384D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.70	25.15	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> OLANZAPINE ODT-WGR [WG]
						<sup>a</sup> Olanzapine Sandoz ODT 15 [SZ]	<sup>a</sup> PRYZEX ODT [RW]
						<sup>a</sup> Zypine ODT [AF]	

**olanzapine 15 mg wafer, 28**

8952E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 11.65	35.35	25.15	<sup>a</sup> Zyprexa Zydis [PB]

**■ OLANZAPINE**

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 20 mg orally disintegrating tablet, 28**

3385E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.10	28.55	<sup>a</sup> APO-Olanzapine ODT [TX]	<sup>a</sup> OLANZAPINE ODT-WGR [WG]
						<sup>a</sup> Olanzapine Sandoz ODT 20 [SZ]	<sup>a</sup> PRYZEX ODT [RW]
						<sup>a</sup> Zypine ODT [AF]	

**olanzapine 20 mg wafer, 28**

8953F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	<sup>B</sup> 11.65	38.75	28.55	<sup>a</sup> Zyprexa Zydis [PB]

**■ OLANZAPINE****Caution** Monitor for post-injection syndrome for at least two hours after each injection.**Note** Special Pricing Arrangements apply.**Authority required (STREAMLINED)****4246**

Schizophrenia

**olanzapine 210 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9294E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*323.17	31.60	Zyprexa Relprevv [PB]

**olanzapine 300 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9295F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*520.57	31.60	Zyprexa Relprevv [PB]

**olanzapine 405 mg modified release injection [1 vial] (& inert substance diluent [3 mL vial], 1 pack**

9303P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	346.82	31.60	Zyprexa Relprevv [PB]

**■ QUETIAPINE****Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5611**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)****5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**quetiapine 150 mg modified release tablet, 60**

5458G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.73	25.18	<sup>a</sup> APX-Quetiapine XR [TY]	<sup>a</sup> Quetiapine Sandoz XR [SZ]
						<sup>a</sup> Quetia XR [OW]	<sup>a</sup> Tevatiapine XR [TB]
			<sup>B</sup> 15.48	39.21	25.18	<sup>a</sup> Seroquel XR [AL]	

**quetiapine 200 mg modified release tablet, 60**

9203J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.59	31.60	<sup>a</sup> APX-Quetiapine XR [TY]	<sup>a</sup> QUETIAPINE-AS XR [RW]
						<sup>a</sup> Quetiapine Sandoz XR [SZ]	<sup>a</sup> Quetia XR [OW]
						<sup>a</sup> Tevatiapine XR [TB]	
			<sup>B</sup> 9.45	44.04	31.60	<sup>a</sup> Seroquel XR [AL]	

**quetiapine 300 mg modified release tablet, 60**

9204K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.59	31.60	<sup>a</sup> APX-Quetiapine XR [TY]	<sup>a</sup> QUETIAPINE-AS XR [RW]
						<sup>a</sup> Quetiapine Sandoz XR [SZ]	<sup>a</sup> Quetia XR [OW]

						<sup>a</sup> Tevatiapine XR [TB]	
			<sup>B</sup> 9.45	50.04	31.60	<sup>a</sup> Seroquel XR [AL]	
<b>quetiapine 400 mg modified release tablet, 60</b>							
9205L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	50.45	31.60	<sup>a</sup> APX-Quetiapine XR [TY] <sup>a</sup> Quetiapine Sandoz XR [SZ] <sup>a</sup> Tevatiapine XR [TB]	<sup>a</sup> QUETIAPINE-AS XR [RW] <sup>a</sup> Quetia XR [OW]
			<sup>B</sup> 9.45	59.90	31.60	<sup>a</sup> Seroquel XR [AL]	
<b>quetiapine 50 mg modified release tablet, 60</b>							
9202H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.72	22.17	<sup>a</sup> APX-Quetiapine XR [TY] <sup>a</sup> Quetiapine Sandoz XR [SZ] <sup>a</sup> Tevatiapine XR [TB]	<sup>a</sup> QUETIAPINE-AS XR [RW] <sup>a</sup> Quetia XR [OW]
			<sup>B</sup> 9.45	30.17	22.17	<sup>a</sup> Seroquel XR [AL]	
<b>quetiapine 100 mg tablet, 90</b>							
8457D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	23.73	25.18	<sup>a</sup> APX-QUETIAPINE [TX] <sup>a</sup> Kaptan [ZS] <sup>a</sup> Quetia 100 [RW] <sup>a</sup> Quetiapine Sandoz Pharma [HX] <sup>a</sup> Syquet [AF]	<sup>a</sup> Blooms The Chemist Quetiapine [BG] <sup>a</sup> Pharmacor Quetiapine 100 [CR] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> QUETIAPINE-WGR [WG]
			<sup>B</sup> 9.45	33.18	25.18	<sup>a</sup> Seroquel [AL]	
<b>quetiapine 200 mg tablet, 90</b>							
8458E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	27.45	28.90	<sup>a</sup> APX-QUETIAPINE [TX] <sup>a</sup> Kaptan [ZS] <sup>a</sup> Quetia 200 [RW] <sup>a</sup> Quetiapine Sandoz Pharma [HX] <sup>a</sup> Syquet [AF]	<sup>a</sup> Blooms The Chemist Quetiapine [BG] <sup>a</sup> Pharmacor Quetiapine 200 [CR] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> QUETIAPINE-WGR [WG]
			<sup>B</sup> 9.45	36.90	28.90	<sup>a</sup> Seroquel [AL]	
<b>quetiapine 300 mg tablet, 60</b>							
8580N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	34.00	31.60	<sup>a</sup> APX-QUETIAPINE [TX] <sup>a</sup> Kaptan [ZS] <sup>a</sup> Quetia 300 [RW] <sup>a</sup> Quetiapine Sandoz Pharma [HX] <sup>a</sup> Syquet [AF]	<sup>a</sup> Blooms The Chemist Quetiapine [BG] <sup>a</sup> Pharmacor Quetiapine 300 [CR] <sup>a</sup> Quetiapine RBX [RA] <sup>a</sup> QUETIAPINE-WGR [WG]
			<sup>B</sup> 9.45	43.45	31.60	<sup>a</sup> Seroquel [AL]	

## ■ QUETIAPINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

### Authority required (STREAMLINED)

**4246**

Schizophrenia

### Authority required (STREAMLINED)

**7927**

Acute mania

### **Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

### Authority required (STREAMLINED)

**5869**

Bipolar I disorder

### **Clinical criteria:**

- The treatment must be maintenance therapy.

# NERVOUS SYSTEM

## quetiapine 25 mg tablet, 60

8456C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	..	..	17.87	19.32	<sup>a</sup> APX-QUETIAPINE [TX]	<sup>a</sup> Blooms The Chemist Quetiapine [BG]
						<sup>a</sup> Kaptan [ZS]	<sup>a</sup> Pharmacor Quetiapine 25 [CR]
						<sup>a</sup> Quetia 25 [RW]	<sup>a</sup> Quetiapine RBX [RA]
						<sup>a</sup> Quetiapine Sandoz Pharma [HX]	<sup>a</sup> QUETIAPINE-WGR [WG]
						<sup>a</sup> Syquet [AF]	
			<sup>B</sup> 11.00	28.87	19.32	<sup>a</sup> Seroquel [AL]	

## Benzamides

### ■ AMISULPRIDE

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

## amisulpride 100 mg/mL oral liquid, 60 mL

8736T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*144.31	31.60	Solian Solution [SW]	

## amisulpride 100 mg tablet, 30

8594H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	18.62	20.07	<sup>a</sup> Amisulpride Sandoz Pharma [HX]	<sup>a</sup> AMISULPRIDE-WGR [WG]
						<sup>a</sup> APO-Amisulpride [TX]	<sup>a</sup> Solian 100 [SW]
						<sup>a</sup> Sulprix [AF]	

## amisulpride 200 mg tablet, 60

8595J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	35.48	31.60	<sup>a</sup> Amisulpride Sandoz Pharma [HX]	<sup>a</sup> AMISULPRIDE-WGR [WG]
						<sup>a</sup> APO-Amisulpride [TX]	<sup>a</sup> Solian 200 [SW]
						<sup>a</sup> Sulprix [AF]	

## amisulpride 400 mg tablet, 60

8596K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	53.39	31.60	<sup>a</sup> Amipride 400 [RW]	<sup>a</sup> Amisulpride Sandoz Pharma [HX]
						<sup>a</sup> AMISULPRIDE-WGR [WG]	<sup>a</sup> APO-Amisulpride [TX]
						<sup>a</sup> Solian 400 [SW]	<sup>a</sup> Sulprix [AF]

## Other antipsychotics

### ■ ARIPIPRAZOLE

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

## aripiprazole 15 mg tablet, 30

8718W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	56.90	31.60	<sup>a</sup> Abilify [OS]	<sup>a</sup> Abyraz [AF]
						<sup>a</sup> APO-Aripiprazole [TX]	<sup>a</sup> Aripiprazole GH [GQ]
						<sup>a</sup> Aripiprazole Sandoz [SZ]	<sup>a</sup> ARIPIPRAZOLE-WGR [WG]
						<sup>a</sup> ARIZOLE [RW]	

## aripiprazole 20 mg tablet, 30

8719X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	66.34	31.60	<sup>a</sup> Abilify [OS]	<sup>a</sup> Abyraz [AF]
						<sup>a</sup> APO-Aripiprazole [TX]	<sup>a</sup> Aripiprazole GH [GQ]
						<sup>a</sup> Aripiprazole Sandoz [SZ]	<sup>a</sup> ARIPIPRAZOLE-WGR [WG]
						<sup>a</sup> ARIZOLE [RW]	

## aripiprazole 30 mg tablet, 30

8720Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	77.90	31.60	<sup>a</sup> Abilify [OS]	<sup>a</sup> Abyraz [AF]
						<sup>a</sup> APO-Aripiprazole [TX]	<sup>a</sup> Aripiprazole GH [GQ]
						<sup>a</sup> Aripiprazole Sandoz [SZ]	<sup>a</sup> ARIPIPRAZOLE-WGR [WG]
						<sup>a</sup> ARIZOLE [RW]	

## aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

10224D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	293.37	31.60	Abilify Maintena [LU]	



**aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10219W NP	1	5	..	364.60	31.60	Abilify Maintena [LU]

**aripiprazole 10 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8717T NP	1	5	..	44.07	31.60	<sup>a</sup> Abilify [OS] <sup>a</sup> APO-Aripiprazole [TX] <sup>a</sup> Aripiprazole Sandoz [SZ] <sup>a</sup> ARIZOLE [RW]	<sup>a</sup> Abyraz [AF] <sup>a</sup> Aripiprazole GH [GQ] <sup>a</sup> ARIPIPAZOLE-WGR [WG]

**■ BREXPIPAZOLE****Authority required (STREAMLINED)****4246**

Schizophrenia

**brexpiprazole 1 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11189X NP	1	..	..	139.42	31.60	Rexulti [LU]

**brexpiprazole 2 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11188W NP	1	5	..	139.42	31.60	Rexulti [LU]

**brexpiprazole 3 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11190Y NP	1	5	..	139.42	31.60	Rexulti [LU]

**brexpiprazole 4 mg tablet, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11184P NP	1	5	..	139.42	31.60	Rexulti [LU]

**■ CARIPRAZINE****Authority required (STREAMLINED)****4246**

Schizophrenia

**cariprazine 6 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12622H NP	1	5	..	102.44	31.60	Reagila [CS]

**cariprazine 1.5 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12652X NP	1	5	..	102.44	31.60	Reagila [CS]

**cariprazine 3 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12619E NP	1	5	..	102.44	31.60	Reagila [CS]

**cariprazine 4.5 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12653Y NP	1	5	..	102.44	31.60	Reagila [CS]

**■ PALIPERIDONE****Authority required (STREAMLINED)****4246**

Schizophrenia

**paliperidone 100 mg modified release injection, 1 syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5107T NP	1	5	..	284.63	31.60	Invega Sustenna [JC]

**paliperidone 150 mg modified release injection, 1 syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5109X NP	1	5	..	284.63	31.60	Invega Sustenna [JC]

**paliperidone 25 mg modified release injection, 1 syringe**

5100K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	95.72	31.60	Invega Sustenna [JC]

**paliperidone 50 mg modified release injection, 1 syringe**

5102M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	181.21	31.60	Invega Sustenna [JC]

**paliperidone 75 mg modified release injection, 1 syringe**

5103N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	233.18	31.60	Invega Sustenna [JC]

**paliperidone 3 mg modified release tablet, 28**

9140C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	55.49	31.60	Invega [JC]

**paliperidone 6 mg modified release tablet, 28**

9141D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	98.38	31.60	Invega [JC]

**paliperidone 9 mg modified release tablet, 28**

9142E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	5	..	142.21	31.60	Invega [JC]

**■ PALIPERIDONE**

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****13049**

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months; OR
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

11085K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	1	..	526.70	31.60	Invega Trinza [JC]

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

11072R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	1	..	682.63	31.60	Invega Trinza [JC]

**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

11094X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	1	..	835.87	31.60	Invega Trinza [JC]

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

11066K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>(NP)</b>	1	1	..	835.87	31.60	Invega Trinza [JC]

**■ PALIPERIDONE**

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****13082**

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle; OR
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

**paliperidone 700 mg/3.5 mL modified release injection, 3.5 mL syringe**

13053B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1606.43	31.60	Invega Hafyera [JC]

**paliperidone 1 g/5 mL modified release injection, 5 mL syringe**

13046P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1606.43	31.60	Invega Hafyera [JC]

**■ RISPERIDONE****Authority required (STREAMLINED)****4246**

Schizophrenia

**Authority required (STREAMLINED)****5907**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

**risperidone 1 mg tablet, 60**

3169T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.87	19.32	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 2 mg tablet, 60**

3170W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.03	24.48	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 3 mg tablet, 60**

3171X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.22	29.67	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 4 mg tablet, 60**

3172Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.37	31.60	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Rispa [RW]	<sup>a</sup> Risperdal [JC]
						<sup>a</sup> Risperidone Sandoz [SZ]	<sup>a</sup> Rispernia [ZS]
						<sup>a</sup> Rixadone [AF]	

**risperidone 1 mg/mL oral liquid, 100 mL**

8100H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	114.99	31.60	<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Lupin [GQ]
						<sup>a</sup> Rixadone [AF]	

**■ RISPERIDONE****Authority required (STREAMLINED)****6898**

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

**16048**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be at least 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 1 mg tablet, 60**

8789N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.87	19.32	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 2 mg tablet, 60**

9079W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	23.03	24.48	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 1 mg/mL oral liquid, 100 mL**

9293D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	‡1	2	..	114.99	31.60	<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Lupin [GQ]
						<sup>a</sup> Rixadone [AF]	

▪ **RISPERIDONE**

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

**Authority required (STREAMLINED)**

**5912**

Bipolar I disorder

**Clinical criteria:**

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8780D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*186.57	31.60	Risperdal Consta [JC]

**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8781E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*240.37	31.60	Risperdal Consta [JC]

**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

8782F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*293.61	31.60	Risperdal Consta [JC]

▪ **RISPERIDONE**

**Note** For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**4246**

Schizophrenia

**risperidone 500 microgram tablet, 20**

1846E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*22.20	23.65	<sup>a</sup> Risperdal [JC]

**risperidone 500 microgram tablet, 60**

8869T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.20	23.65	<sup>a</sup> APO-Risperidone [TX] <sup>a</sup> Ozidal [RA] <sup>a</sup> Risperidone Sandoz [SZ] <sup>a</sup> Rixadone [AF]	<sup>a</sup> NOUMED RISPERIDONE [VO] <sup>a</sup> Rispera [RW] <sup>a</sup> Rispernia [ZS]

**■ RISPERIDONE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****16231**

Schizophrenia

For a patient switching from oral risperidone, the prescriber must determine the patient dosage of this drug based on the current dose of oral risperidone according to the dose transition table in the Therapeutic Goods Administration (TGA) approved Product Information.

**risperidone 75 mg modified release injection [1 syringe] (&) inert substance diluent [0.383 mL syringe], 1 pack**

14686Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	215.30	31.60	Risvan [SE]

**risperidone 100 mg modified release injection [1 syringe] (&) inert substance diluent [0.49 mL syringe], 1 pack**

14688C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	262.65	31.60	Risvan [SE]

**■ RISPERIDONE**

**Note** For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****6898**

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)****16048**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be at least 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 500 microgram tablet, 20**

1842Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	2	..	*22.20	23.65	<sup>a</sup> Risperdal [JC]

**risperidone 500 microgram tablet, 60**

8787L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	22.20	23.65	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperidone Sandoz [SZ]	<sup>a</sup> Rispernia [ZS]
						<sup>a</sup> Rixadone [AF]	

**■ RISPERIDONE**

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****10020**

Behavioural disturbances

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
  - Patient must have dementia of the Alzheimer type, **AND**
  - Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
  - Patient must not receive more than 12 weeks of treatment under this restriction.
- A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

**risperidone 1 mg tablet, 60**

11877D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.87	19.32	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

**risperidone 1 mg/mL oral liquid, 100 mL**

11874Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	2	..	114.99	31.60	<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Lupin [GQ]
						<sup>a</sup> Rixadone [AF]	

**■ RISPERIDONE**

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

### risperidone 1 mg tablet, 60

11879F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.87	19.32	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Sandoz [SZ]
						<sup>a</sup> Rispernia [ZS]	<sup>a</sup> Rixadone [AF]

### risperidone 1 mg/mL oral liquid, 100 mL

11882J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	2	..	114.99	31.60	<sup>a</sup> Risperdal [JC]	<sup>a</sup> Risperidone Lupin [GQ]
						<sup>a</sup> Rixadone [AF]	

## ■ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

10020

Behavioural disturbances

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

### risperidone 500 microgram tablet, 20

11872W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	2	..	*22.20	23.65	<sup>a</sup> Risperdal [JC]

### risperidone 500 microgram tablet, 60

11869Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	22.20	23.65	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperidone Sandoz [SZ]	<sup>a</sup> Rispernia [ZS]
						<sup>a</sup> Rixadone [AF]	

## ■ RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

#### **Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

### risperidone 500 microgram tablet, 20

11873X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	2	..	*22.20	23.65	<sup>a</sup> Risperdal [JC]

### risperidone 500 microgram tablet, 60

11881H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	22.20	23.65	<sup>a</sup> APO-Risperidone [TX]	<sup>a</sup> NOUMED RISPERIDONE [VO]
						<sup>a</sup> Ozidal [RA]	<sup>a</sup> Rispa [RW]
						<sup>a</sup> Risperidone Sandoz [SZ]	<sup>a</sup> Rispernia [ZS]
						<sup>a</sup> Rixadone [AF]	

## ANXIOLYTICS

### Benzodiazepine derivatives

#### ■ ALPRAZOLAM

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

Panic disorder

#### Clinical criteria:

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

### alprazolam 250 microgram tablet, 10

11205R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.74	23.19	Kalma 0.25 [AF]

### alprazolam 500 microgram tablet, 10

11187T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.20	23.65	<sup>a</sup> Alprax 0.5 [AS]	<sup>a</sup> Kalma 0.5 [AF]

### alprazolam 1 mg tablet, 10

11186R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.74	24.19	<sup>a</sup> Alprax 1 [AS]	<sup>a</sup> Kalma 1 [AF]

#### ■ DIAZEPAM

### diazepam 2 mg tablet, 50

5071X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	<sup>a</sup> APX-Diazepam [TY]	<sup>a</sup> DIAZEPAM-WGR [WG]
						<sup>a</sup> Valpam 2 [RW]	
			<sup>B</sup> 2.78	19.15	17.82	<sup>a</sup> Antenex 2 [AF]	

### diazepam 5 mg tablet, 50

5072Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.37	17.82	<sup>a</sup> Antenex 5 [AF]	<sup>a</sup> APX-Diazepam [TY]
						<sup>a</sup> DIAZEPAM-WGR [WG]	<sup>a</sup> NOUMED DIAZEPAM [VO]
						<sup>a</sup> Valpam 5 [RW]	
			<sup>B</sup> 3.08	19.45	17.82	<sup>a</sup> Valium [IX]	

#### ■ DIAZEPAM

#### Authority required

Chronic spasticity

#### Population criteria:



- Patient must be under 18 years of age.

**diazepam 10 mg/10 mL oral liquid, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2669L	±1	..	..	45.32	31.60	Diazepam Elixir [ON]

**■ DIAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

- (i) the treatment of disabling spasticity; or
- (ii) malignant neoplasia (late stage); or
- (iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
- (iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 2 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3161J	1	..	..	16.37	17.82	<sup>a</sup> APX-Diazepam [TY] <sup>a</sup> Valpam 2 [RW]	<sup>a</sup> DIAZEPAM-WGR [WG]
			<sup>b</sup> 2.78	19.15	17.82	<sup>a</sup> Antenex 2 [AF]	

**diazepam 5 mg tablet, 50**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3162K	1	..	..	16.37	17.82	<sup>a</sup> Antenex 5 [AF] <sup>a</sup> DIAZEPAM-WGR [WG] <sup>a</sup> Valpam 5 [RW]	<sup>a</sup> APX-Diazepam [TY] <sup>a</sup> NOUMED DIAZEPAM [VO]
			<sup>b</sup> 3.08	19.45	17.82	<sup>a</sup> Valium [IX]	

**■ OXAZEPAM****oxazepam 15 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5192G	1	..	..	16.17	17.62	<sup>a</sup> Alepam 15 [AF]	<sup>a</sup> Serepax [AS]

**oxazepam 30 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5193H	1	..	..	16.17	17.62	<sup>a</sup> Alepam 30 [AF] <sup>a</sup> OXAZEPAM-WGR [WG]	<sup>a</sup> APO-Oxazepam [TX]
			<sup>b</sup> 0.84	17.01	17.62	<sup>a</sup> Murelax [RW]	
			<sup>b</sup> 3.92	20.09	17.62	<sup>a</sup> Serepax [AS]	

**■ OXAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam.

**oxazepam 15 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3132W	1	..	..	16.17	17.62	<sup>a</sup> Alepam 15 [AF]	<sup>a</sup> Serepax [AS]

**oxazepam 30 mg tablet, 25**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3133X	1	..	..	16.17	17.62	<sup>a</sup> Alepam 30 [AF] <sup>a</sup> OXAZEPAM-WGR [WG]	<sup>a</sup> APO-Oxazepam [TX]
			<sup>b</sup> 0.84	17.01	17.62	<sup>a</sup> Murelax [RW]	
			<sup>b</sup> 3.92	20.09	17.62	<sup>a</sup> Serepax [AS]	

**■ OXAZEPAM****Authority required**

Malignant neoplasia (late stage)

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**oxazepam 15 mg tablet, 25**

3134Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Alepam 15 [AF]	<sup>a</sup> Serepax [AS]

**oxazepam 30 mg tablet, 25**

3135B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Alepam 30 [AF] <sup>a</sup> OXAZEPAM-WGR [WG]	<sup>a</sup> APO-Oxazepam [TX]
			<sup>B</sup> 1.68	*20.57	20.34	<sup>a</sup> Murelax [RW]	
			<sup>B</sup> 7.84	*26.73	20.34	<sup>a</sup> Serepax [AS]	

**HYPNOTICS AND SEDATIVES***Benzodiazepine derivatives***■ MIDAZOLAM**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Generalized convulsive status epilepticus

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of status epilepticus, **AND**
- Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years.

**Population criteria:**

- Patient must be at least one year of age.

**Clinical criteria:**

- The treatment must initiated by a specialist physician experienced in the treatment of epilepsy.

At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

**midazolam 10 mg/mL oral liquid, 1 mL syringe**

14270C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*279.41	31.60	Zyamis [IX]

**midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe**

14292F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*279.41	31.60	Zyamis [IX]

**midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe**

14238J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*279.41	31.60	Zyamis [IX]

**■ MIDAZOLAM**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Generalized convulsive status epilepticus

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

**midazolam 10 mg/mL oral liquid, 1 mL syringe**

14299N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*279.41	31.60	Zyamis [IX]

**midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe**

14293G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*279.41	31.60	Zyamis [IX]

**midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe**

14291E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*279.41	31.60	Zyamis [IX]

**■ NITRAZEPAM****nitrazepam 5 mg tablet, 25**

5189D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> Alodorm [AF]	<sup>a</sup> Mogadon [IL]

**■ NITRAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam.

**nitrazepam 5 mg tablet, 25**

2723H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.17	17.62	<sup>a</sup> Alodorm [AF]	<sup>a</sup> Mogadon [IL]

**■ NITRAZEPAM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> Alodorm [AF]	<sup>a</sup> Mogadon [IL]

**■ TEMAZEPAM****temazepam 10 mg tablet, 25**

5221T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.17	17.62	<sup>a</sup> APO-Temazepam [TX] <sup>a</sup> TEMAZEPAM-WGR [WG]	<sup>a</sup> Temaze [AF] <sup>a</sup> Temtabs [LN]
			<sup>b</sup> 5.07	21.24	17.62	<sup>a</sup> Normison [AS]	

**■ TEMAZEPAM**

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

**Restricted benefit**

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**temazepam 10 mg tablet, 25**

2089Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	16.17	17.62	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> TEMAZEPAM-WGR [WG]	<sup>a</sup> Temtabs [LN]
			<sup>B</sup> 5.07	21.24	17.62	<sup>a</sup> Normison [AS]	

▪ **TEMAZEPAM**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

2088X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.89	20.34	<sup>a</sup> APO-Temazepam [TX]	<sup>a</sup> Temaze [AF]
						<sup>a</sup> TEMAZEPAM-WGR [WG]	<sup>a</sup> Temtabs [LN]
			<sup>B</sup> 10.14	*29.03	20.34	<sup>a</sup> Normison [AS]	

*Melatonin receptor agonists*

▪ **MELATONIN**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** A developmental specialist is a medical practitioner who is a member of the Neurodevelopmental and Behavioural Paediatric Society of Australasia.

**Note** Increases in the maximum quantity to provide sufficient treatment duration for 30 days treatment per dispensing at the maximum recommended dose as per the approved Product Information, may be sought.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Insomnia

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have Smith-Magenis Syndrome confirmed by genetic testing, **AND**
- The condition must be inadequately responsive to sleep hygiene measures, resulting in the patient experiencing a period of at least 12 consecutive weeks of impaired sleep (see definition of impaired sleep below).

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types.

**Population criteria:**

- Patient must be at least 2 years of age, but yet to turn 18 years of age, at treatment initiation with this drug.

Definition:

For the purposes of administering this restriction, Smith-Magenis Syndrome is confirmed by the deletion or variation of the retinoic acid induced 1 (RAI1) gene on chromosome 17p11.2

**Definition:**For the purposes of administering this restriction, impaired sleep is at least one of:(i) less than 6 hours of continuous sleep on at least 3 occasions over a given 5-day interval; (ii) taking at least half an hour to fall asleep on at least 3 occasions over a given 5-day interval.

Prior to seeking authorisation for this pharmaceutical benefit, document the amount of continuous sleep/sleep latency in the patient's medical records for a period of 2 consecutive weeks, but ensure the impairment has been observed for at least 12 consecutive weeks. The documented values (averages) will form baseline measurements upon which the extent of response to treatment is to be considered under the Continuing treatment listing.

The observations of continuous sleep/sleep latency may be based on any of the following, including a mix of: patient self-reporting, parental observation, documented medical history, sleep studies conducted by health professionals.

**Authority required**

Insomnia

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have experienced/maintained a clinically meaningful response (as defined below) to the preceding supply of this drug - document the response improvement in the patient's medical records, **AND**
- The treatment must have commenced between the ages of 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Treatment must cease if a patient is unable to achieve a clinically meaningful response on the maximum dose of melatonin specified in the Product Information.

**Definition:**

A clinically meaningful response to this drug is defined as at least one of:

- (i) an increase in total sleep time of at least 45 minutes per night on average from baseline;
- (ii) a decrease in the time it takes to fall asleep by at least 15 minutes per night on average from baseline.

**melatonin 1 mg modified release tablet, 60**

14188R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	72.60	31.60	Slenyto [AS]

**melatonin 5 mg modified release tablet, 30**

14211Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	155.23	31.60	Slenyto [AS]

## PSYCHOANALEPTICS

### ANTIDEPRESSANTS

*Non-selective monoamine reuptake inhibitors*

#### AMITRIPTYLINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**amitriptyline hydrochloride 10 mg tablet, 50**

2417F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.70	18.15	<sup>a</sup> Amitriptyline Lupin [GQ]	<sup>a</sup> Amitriptyline Viatrix 10 [AL]
						<sup>a</sup> AMITRIPTYLINE-WGR [WG]	<sup>a</sup> APX-Amitriptyline [TY]
						<sup>a</sup> ENTRIP [RW]	
			<sup>b</sup> 1.82	18.52	18.15	<sup>a</sup> Endep 10 [AF]	

**amitriptyline hydrochloride 25 mg tablet, 50**

2418G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.88	18.33	<sup>a</sup> Amitriptyline Lupin [GQ]	<sup>a</sup> Amitriptyline Viatrix 25 [AL]
						<sup>a</sup> AMITRIPTYLINE-WGR [WG]	<sup>a</sup> APX-Amitriptyline [TY]
						<sup>a</sup> ENTRIP [RW]	
			<sup>b</sup> 1.82	18.70	18.33	<sup>a</sup> Endep 25 [AF]	

**amitriptyline hydrochloride 50 mg tablet, 50**

2429W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.25	18.70	<sup>a</sup> Amitriptyline Lupin [GQ]	<sup>a</sup> Amitriptyline Viatrix 50 [AL]
						<sup>a</sup> APX-Amitriptyline [TY]	<sup>a</sup> ENTRIP [RW]
						<sup>a</sup> Endep 50 [AF]	
			<sup>b</sup> 1.82	19.07	18.70		

## ■ CLOMIPRAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Cataplexy

**Clinical criteria:**

- The condition must be associated with narcolepsy.

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Phobic disorders

**Population criteria:**

- Patient must be an adult.

**clomipramine hydrochloride 25 mg tablet, 50**

1561E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	18.52	19.97	<sup>a</sup> APO-Clomipramine [TX]	<sup>a</sup> CLOMIPRAMINE-WGR [WG]
						<sup>a</sup> Placil [AF]	
			<sup>B</sup> 3.66	22.18	19.97	<sup>a</sup> Anafranil 25 [PB]	

## ■ DOSULEPIN (DOTHIEPIN)

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**dosulepin (dothiepin) hydrochloride 25 mg capsule, 50**

1357K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	16.76	18.21	<sup>a</sup> Dosulepin Viatrix [MQ]
			<sup>B</sup> 1.81	18.57	18.21	<sup>a</sup> Dothep 25 [AF]

**dosulepin (dothiepin) hydrochloride 75 mg tablet, 30**

1358L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.76	18.21	<sup>a</sup> Dosulepin Viatrix 75 [AL]	<sup>a</sup> Dothep 75 [AF]

## ■ IMIPRAMINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**imipramine hydrochloride 10 mg tablet, 50**

2420J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.84	19.29	Tofranil 10 [GH]

## ■ IMIPRAMINE

**Note** Pharmaceutical benefits that have the form imipramine hydrochloride 25 mg tablet in a pack size of 50 can be substituted for a pack size of 100 in the case of a shortage.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**imipramine hydrochloride 25 mg tablet, 50**

2421K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	21.10	22.55	<sup>a</sup> Tofranil 25 [GH]

**imipramine hydrochloride 25 mg tablet, 100**

12113M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	2	..	*27.67	29.12	<sup>a</sup> Imipramine (Leading) [QY]

## ■ NORTRIPTYLINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy is contraindicated.

**nortriptyline 10 mg tablet, 50**

2522R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	2	..	17.42	18.87	Allegron [RW]	

**nortriptyline 25 mg tablet, 50**

2523T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
<b>NP</b>	1	2	..	18.33	19.78	Allegron [RW]	

*Selective serotonin reuptake inhibitors***■ CITALOPRAM****Restricted benefit**

Major depressive disorders

**citalopram 10 mg tablet, 28**

8702B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> Celapram [AF] <sup>a</sup> Talam [RW]	<sup>a</sup> CITALOPRAM-WGR [WG]

**citalopram 20 mg tablet, 28**

8220P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Celapram [AF] <sup>a</sup> CITALOPRAM-WGR [WG] <sup>a</sup> Talam [RW]	<sup>a</sup> APX-Citalopram [TY] <sup>a</sup> Citalopram Sandoz [SZ] <sup>a</sup> NOUMED CITALOPRAM [VO]
			<sup>B</sup> 13.15	29.32	17.62	<sup>a</sup> Cipramil [LU]	

**citalopram 40 mg tablet, 28**

8703C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.21	17.66	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Citalopram Sandoz [SZ] <sup>a</sup> NOUMED CITALOPRAM [VO]	<sup>a</sup> Celapram [AF] <sup>a</sup> CITALOPRAM-WGR [WG] <sup>a</sup> Talam [RW]

**■ CITALOPRAM****Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**citalopram 10 mg tablet, 28**

14313H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> Celapram [AF] <sup>a</sup> Talam [RW]	<sup>a</sup> CITALOPRAM-WGR [WG]

**citalopram 20 mg tablet, 28**

14490P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Celapram [AF] <sup>a</sup> CITALOPRAM-WGR [WG] <sup>a</sup> Talam [RW]	<sup>a</sup> APX-Citalopram [TY] <sup>a</sup> Citalopram Sandoz [SZ] <sup>a</sup> NOUMED CITALOPRAM [VO]
			<sup>B</sup> 26.30	*45.19	20.34	<sup>a</sup> Cipramil [LU]	

**citalopram 40 mg tablet, 28**

14518D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.97	20.42	<sup>a</sup> APO-Citalopram [TX] <sup>a</sup> Citalopram Sandoz [SZ] <sup>a</sup> NOUMED CITALOPRAM [VO]	<sup>a</sup> Celapram [AF] <sup>a</sup> CITALOPRAM-WGR [WG] <sup>a</sup> Talam [RW]

**■ ESCITALOPRAM****Restricted benefit**

Major depressive disorders

**escitalopram 10 mg tablet, 28**

8700X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Cilopam-S [ZS] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 10 [RW]
			<sup>B</sup> 14.18	30.35	17.62	<sup>a</sup> Lexapro [LU]	

**escitalopram 20 mg tablet, 28**

8701Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Cilopam-S [ZS] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 20 [RW]
			<sup>B</sup> 14.53	30.70	17.62	<sup>a</sup> Lexapro [LU]	

**■ ESCITALOPRAM****Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**escitalopram 10 mg tablet, 28**

14349F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Cilopam-S [ZS] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 10 [RW]
			<sup>B</sup> 28.36	*47.25	20.34	<sup>a</sup> Lexapro [LU]	

**escitalopram 20 mg tablet, 28**

14415Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Cilopam-S [ZS] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 20 [RW]
			<sup>B</sup> 29.06	*47.95	20.34	<sup>a</sup> Lexapro [LU]	

**■ ESCITALOPRAM****Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)



**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

9432K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 10 [RW]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]
			<sup>B</sup> 14.18	30.35	17.62	<sup>a</sup> Lexapro [LU]	

**escitalopram 20 mg tablet, 28**

9433L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.62	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 20 [RW]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF]
			<sup>B</sup> 14.53	30.70	17.62	<sup>a</sup> Lexapro [LU]	

**■ ESCITALOPRAM****Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

14519E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 10 [RW]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF] <sup>a</sup> LoxaLate [AF]
			<sup>B</sup> 28.36	*47.25	20.34	<sup>a</sup> Lexapro [LU]	

**escitalopram 20 mg tablet, 28**

14416R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Escitalopram [TX] <sup>a</sup> Blooms Escitalopram [BG] <sup>a</sup> Escitalopram Sandoz [HX] <sup>a</sup> Lexam 20 [RW]	<sup>a</sup> APX-Escitalopram [TY] <sup>a</sup> Escitalopram GH [HQ] <sup>a</sup> Esipram [CF]
			<sup>B</sup> 29.06	*47.95	20.34	<sup>a</sup> Lexapro [LU]	

▪ **ESCITALOPRAM****Restricted benefit**

Major depressive disorders

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

10181W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	39.43	31.60	Lexapro [LU]

▪ **ESCITALOPRAM****Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

14546N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	2	..	*65.41	31.60	Lexapro [LU]

**FLUOXETINE****Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

1434L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	<sup>a</sup> APO-Fluoxetine [TX]	<sup>a</sup> Blooms the Chemist Fluoxetine [BG]
						<sup>a</sup> FLUOTEX [RF]	<sup>a</sup> Fluoxetine APOTEX [TY]
						<sup>a</sup> Fluoxetine generichealth [GQ]	<sup>a</sup> Fluoxetine Sandoz [SZ]
						<sup>a</sup> Zactin [AF]	

**fluoxetine 20 mg tablet, 28**

8270G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.22	18.67	Zactin Tablet [AF]

**FLUOXETINE****Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluoxetine 20 mg capsule, 28**

14548Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*20.99	22.44	<sup>a</sup> APO-Fluoxetine [TX]	<sup>a</sup> Blooms the Chemist Fluoxetine [BG]
						<sup>a</sup> FLUOTEX [RF]	<sup>a</sup> Fluoxetine APOTEX [TY]
						<sup>a</sup> Fluoxetine generichealth [GQ]	<sup>a</sup> Fluoxetine Sandoz [SZ]
						<sup>a</sup> Zactin [AF]	

**fluoxetine 20 mg tablet, 28**

14717N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*20.99	22.44	Zactin Tablet [AF]

## ■ FLUVOXAMINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**fluvoxamine maleate 100 mg tablet, 30**

8174F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.03	23.48	<sup>a</sup> APO-Fluvoxamine [TX]	<sup>a</sup> Faverin 100 [RW]
						<sup>a</sup> FLUVOXAMINE-WGR [WG]	<sup>a</sup> Movox 100 [AF]
			<sup>B</sup> 3.50	25.53	23.48	<sup>a</sup> Luvox [GO]	

**fluvoxamine maleate 50 mg tablet, 30**

8512B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.12	20.57	<sup>a</sup> APO-Fluvoxamine [TX]	<sup>a</sup> Faverin 50 [RW]
						<sup>a</sup> FLUVOXAMINE-WGR [WG]	<sup>a</sup> Movox 50 [AL]
			<sup>B</sup> 3.50	22.62	20.57	<sup>a</sup> Luvox [GO]	

## ■ FLUVOXAMINE

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluvoxamine maleate 100 mg tablet, 30**

14314J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*30.61	31.60	<sup>a</sup> APO-Fluvoxamine [TX]	<sup>a</sup> Faverin 100 [RW]
						<sup>a</sup> FLUVOXAMINE-WGR [WG]	<sup>a</sup> Movox 100 [AF]
			<sup>B</sup> 7.00	*37.61	31.60	<sup>a</sup> Luvox [GO]	

**fluvoxamine maleate 50 mg tablet, 30**

14488M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*24.79	26.24	<sup>a</sup> APO-Fluvoxamine [TX]	<sup>a</sup> Faverin 50 [RW]
						<sup>a</sup> FLUVOXAMINE-WGR [WG]	<sup>a</sup> Movox 50 [AL]
			<sup>B</sup> 7.00	*31.79	26.24	<sup>a</sup> Luvox [GO]	

## ■ PAROXETINE

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**paroxetine 20 mg tablet, 30**

2242B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Paroxetine [TX]	<sup>a</sup> APX-Paroxetine [TY]
						<sup>a</sup> Blooms The Chemist Paroxetine [BG]	<sup>a</sup> Extine 20 [RW]
						<sup>a</sup> Noumed Paroxetine [VO]	<sup>a</sup> Paroxetine GH [GQ]
						<sup>a</sup> Paroxetine Sandoz [SZ]	<sup>a</sup> PAROXETINE-WGR [WG]
						<sup>a</sup> Paxtine [AF]	
						<sup>B</sup> 2.58	
				19.80	18.67	<sup>a</sup> Aropax [AS]	

## ■ PAROXETINE

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**paroxetine 20 mg tablet, 30**

14367E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*20.99	22.44	<sup>a</sup> APO-Paroxetine [TX] <sup>a</sup> Blooms The Chemist Paroxetine [BG] <sup>a</sup> Noumed Paroxetine [VO] <sup>a</sup> Paroxetine Sandoz [SZ] <sup>a</sup> Paxtine [AF]	<sup>a</sup> APX-Paroxetine [TY] <sup>a</sup> Extine 20 [RW] <sup>a</sup> Paroxetine GH [GQ] <sup>a</sup> PAROXETINE-WGR [WG]
			<sup>B</sup> 5.16	*26.15	22.44	<sup>a</sup> Aropax [AS]	

**■ SERTRALINE****Restricted benefit**

Major depressive disorders

**sertraline 100 mg tablet, 30**

2237R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Eleva 100 [AF] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> SERTRALINE-WGR [WG]	<sup>a</sup> Blooms The Chemist Sertraline [BG] <sup>a</sup> Sertra 100 [RW] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Setrona [RA]
			<sup>B</sup> 6.78	22.95	17.62	<sup>a</sup> Zoloft [UJ]	

**sertraline 50 mg tablet, 30**

2236Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Eleva 50 [AF] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> SERTRALINE-WGR [WG]	<sup>a</sup> Blooms The Chemist Sertraline [BG] <sup>a</sup> Sertra 50 [RW] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Setrona [RA]
			<sup>B</sup> 6.78	22.95	17.62	<sup>a</sup> Zoloft [UJ]	

**■ SERTRALINE****Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sertraline 100 mg tablet, 30**

14506L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Eleva 100 [AF] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> SERTRALINE-WGR [WG]	<sup>a</sup> Blooms The Chemist Sertraline [BG] <sup>a</sup> Sertra 100 [RW] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Setrona [RA]
			<sup>B</sup> 13.56	*32.45	20.34	<sup>a</sup> Zoloft [UJ]	

**sertraline 50 mg tablet, 30**

14400X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Sertraline [TX] <sup>a</sup> Eleva 50 [AF] <sup>a</sup> Sertraline generichealth [GQ] <sup>a</sup> SERTRALINE-WGR [WG]	<sup>a</sup> Blooms The Chemist Sertraline [BG] <sup>a</sup> Sertra 50 [RW] <sup>a</sup> Sertraline Sandoz [SZ] <sup>a</sup> Setrona [RA]
			<sup>B</sup> 13.56	*32.45	20.34	<sup>a</sup> Zoloft [UJ]	

**■ SERTRALINE****Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; OR

- The treatment must be for use when other treatments are inappropriate.

**sertraline 100 mg tablet, 30**

8837D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Sertraline [TX]	<sup>a</sup> Blooms The Chemist Sertraline [BG]
						<sup>a</sup> Eleva 100 [AF]	<sup>a</sup> Sertra 100 [RW]
						<sup>a</sup> Sertraline generichealth [GQ]	<sup>a</sup> Sertraline Sandoz [SZ]
						<sup>a</sup> SERTRALINE-WGR [WG]	
			<sup>B</sup> 6.78	22.95	17.62	<sup>a</sup> Zoloft [UJ]	

**sertraline 50 mg tablet, 30**

8836C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	16.17	17.62	<sup>a</sup> APO-Sertraline [TX]	<sup>a</sup> Blooms The Chemist Sertraline [BG]
						<sup>a</sup> Eleva 50 [AF]	<sup>a</sup> Sertra 50 [RW]
						<sup>a</sup> Sertraline generichealth [GQ]	<sup>a</sup> Sertraline Sandoz [SZ]
						<sup>a</sup> SERTRALINE-WGR [WG]	
			<sup>B</sup> 6.78	22.95	17.62	<sup>a</sup> Zoloft [UJ]	

**■ SERTRALINE****Restricted benefit**

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Panic disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

**sertraline 100 mg tablet, 30**

14404D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Sertraline [TX]	<sup>a</sup> Blooms The Chemist Sertraline [BG]
						<sup>a</sup> Eleva 100 [AF]	<sup>a</sup> Sertra 100 [RW]
						<sup>a</sup> Sertraline generichealth [GQ]	<sup>a</sup> Sertraline Sandoz [SZ]
						<sup>a</sup> SERTRALINE-WGR [WG]	
			<sup>B</sup> 13.56	*32.45	20.34	<sup>a</sup> Zoloft [UJ]	

**sertraline 50 mg tablet, 30**

14403C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*18.89	20.34	<sup>a</sup> APO-Sertraline [TX]	<sup>a</sup> Blooms The Chemist Sertraline [BG]
						<sup>a</sup> Eleva 50 [AF]	<sup>a</sup> Sertra 50 [RW]
						<sup>a</sup> Sertraline generichealth [GQ]	<sup>a</sup> Sertraline Sandoz [SZ]
						<sup>a</sup> SERTRALINE-WGR [WG]	
			<sup>B</sup> 13.56	*32.45	20.34	<sup>a</sup> Zoloft [UJ]	

**Monoamine oxidase inhibitors, non-selective****■ PHENELZINE****Caution** This drug is an irreversible monoamine oxidase inhibitor.**Restricted benefit**

Depression

**Clinical criteria:**

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**phenelzine 15 mg tablet, 60**

13148B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*174.31	31.60	Nardil (Canada) [DZ]

**phenelzine 15 mg tablet, 100**

2856H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	67.26	31.60	Nardil [NG]

**■ TRANYLCPROMINE****Caution** This drug is an irreversible monoamine oxidase inhibitor.

**tranylcypromine 10 mg tablet, 50**

2444P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	2	..	51.78	31.60	Parnate [GH]	

**■ TRANYLCYPROMINE**

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**tranylcypromine 10 mg tablet, 50**

14401Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	2	1	..	*90.11	31.60	Parnate [GH]	

***Monoamine oxidase A inhibitors*****■ MOCLOBEMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**moclobemide 150 mg tablet, 60**

1900B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	1	5	..	20.06	21.51	<sup>a</sup> Amira 150 [AF]		<sup>a</sup> Clobemix [XT]
						<sup>a</sup> Moclobemide Sandoz [SZ]		<sup>a</sup> MOCLOBEMIDE-WGR [WG]
				<sup>B</sup> 2.03	22.09	<sup>a</sup> Aurorix [GO]		

**moclobemide 300 mg tablet, 60**

8003F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	1	5	..	24.47	25.92	<sup>a</sup> Amira 300 [AF]		<sup>a</sup> Clobemix [XT]
						<sup>a</sup> Moclobemide Sandoz [SZ]		<sup>a</sup> MOCLOBEMIDE-WGR [WG]
				<sup>B</sup> 2.03	26.50	<sup>a</sup> Aurorix 300 mg [GO]		

**■ MOCLOBEMIDE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**moclobemide 150 mg tablet, 60**

14560H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	2	2	..	*26.67	28.12	<sup>a</sup> Amira 150 [AF]		<sup>a</sup> Clobemix [XT]
						<sup>a</sup> Moclobemide Sandoz [SZ]		<sup>a</sup> MOCLOBEMIDE-WGR [WG]
				<sup>B</sup> 4.06	*30.73	<sup>a</sup> Aurorix [GO]		

**moclobemide 300 mg tablet, 60**

14442D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	2	2	..	*35.49	31.60	<sup>a</sup> Amira 300 [AF]		<sup>a</sup> Clobemix [XT]
						<sup>a</sup> Moclobemide Sandoz [SZ]		<sup>a</sup> MOCLOBEMIDE-WGR [WG]
				<sup>B</sup> 4.06	*39.55	<sup>a</sup> Aurorix 300 mg [GO]		

***Other antidepressants*****■ DESVENLAFAXINE**

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**desvenlafaxine 100 mg modified release tablet, 28**

10231L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.98	23.43	<sup>a</sup> BTC Desvenlafaxine [BG] <sup>a</sup> DESVEN [RW] <sup>a</sup> DESVENLAFAXINE-WGR XR [WG]	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

**desvenlafaxine 100 mg modified release tablet, 28**

10245F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	21.98	23.43	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

**desvenlafaxine 100 mg modified release tablet, 28**

9367B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	<sup>B</sup> 3.00	24.98	23.43	<sup>a</sup> Pristiq [PF]

**■ DESVENLAFAXINE**

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**desvenlafaxine 50 mg modified release tablet, 28**

10234P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.40	21.85	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

**desvenlafaxine 50 mg modified release tablet, 28**

10241B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	20.40	21.85	<sup>a</sup> BTC Desvenlafaxine [BG] <sup>a</sup> DESVEN [RW] <sup>a</sup> DESVENLAFAXINE-WGR XR [WG]	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

**desvenlafaxine 50 mg modified release tablet, 28**

9366Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	<sup>B</sup> 2.99	23.39	21.85	<sup>a</sup> Pristiq [PF]

**■ DESVENLAFAXINE**

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**desvenlafaxine 50 mg modified release tablet, 28**

14383B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*27.35	28.80	<sup>a</sup> BTC Desvenlafaxine [BG] <sup>a</sup> DESVEN [RW] <sup>a</sup> DESVENLAFAXINE-WGR XR [WG]	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

**desvenlafaxine 50 mg modified release tablet, 28**

14418W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*27.35	28.80	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

**desvenlafaxine 50 mg modified release tablet, 28**

14451N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	2	<sup>B</sup> 5.98	*33.33	28.80	<sup>a</sup> Pristiq [PF]



## ■ DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14384C NP	2	2	..	*30.51	31.60	<sup>a</sup> APO-Desvenlafaxine MR [TX]	<sup>a</sup> Desvenlafaxine GH XR [GQ]

### desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14489N NP	2	2	..	*30.51	31.60	<sup>a</sup> BTC Desvenlafaxine [BG] <sup>a</sup> DESVEN [RW] <sup>a</sup> DESVENLAFAXINE-WGR XR [WG]	<sup>a</sup> Desfax [AF] <sup>a</sup> Desvenlafaxine Sandoz [SZ]

### desvenlafaxine 100 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14545M NP	2	2	<sup>B</sup> 6.00	*36.51	31.60	<sup>a</sup> Pristiq [PF]

## ■ DULOXETINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

### duloxetine 30 mg enteric capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9155W NP	1	..	..	17.73	19.18	<sup>a</sup> APO-Duloxetine [TX] <sup>a</sup> Duloxetine Sandoz [HX] <sup>a</sup> DYTREX 30 [RW]	<sup>a</sup> Duloxecor [CR] <sup>a</sup> Duloxetine Sandoz 30 [SZ] <sup>a</sup> Tixel 30 [AL]

### duloxetine 60 mg enteric capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9156X NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Duloxetine [TX] <sup>a</sup> Duloxetine Sandoz [HX] <sup>a</sup> DYTREX 60 [RW]	<sup>a</sup> Duloxecor [CR] <sup>a</sup> Duloxetine Sandoz 60 [SZ] <sup>a</sup> Tixel 60 [AL]

## ■ DULOXETINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### duloxetine 60 mg enteric capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14712H NP	2	2	..	*22.07	23.52	<sup>a</sup> APO-Duloxetine [TX] <sup>a</sup> Duloxetine Sandoz [HX] <sup>a</sup> DYTREX 60 [RW]	<sup>a</sup> Duloxecor [CR] <sup>a</sup> Duloxetine Sandoz 60 [SZ] <sup>a</sup> Tixel 60 [AL]

## ■ LITHIUM CARBONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lithium carbonate 250 mg tablet, 200**

3059B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	2	..	49.57	31.60	Lithicarb [AS]	

**lithium carbonate 450 mg modified release tablet, 100**

8290H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*81.13	31.60	Quilonum SR [AS]	

**MIANSERIN**

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe depression

**mianserin hydrochloride 10 mg tablet, 50**

1627P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	21.26	22.71	Lumin 10 [AF]	

**mianserin hydrochloride 20 mg tablet, 50**

1628Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	29.91	31.36	Lumin 20 [AF]	

**MIANSERIN**

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe depression

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mianserin hydrochloride 10 mg tablet, 50**

14366D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*29.07	30.52	Lumin 10 [AF]	

**mianserin hydrochloride 20 mg tablet, 50**

14505K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*46.37	31.60	Lumin 20 [AF]	

**MIRTAZAPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**mirtazapine 15 mg tablet, 30**

9365X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.40	17.85	<sup>a</sup> APX-Mirtazapine [TY] <sup>a</sup> Blooms The Chemist Mirtazapine [BG] <sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> Axit 15 [AF] <sup>a</sup> MIRTANZA [RF] <sup>a</sup> MIRTAZAPINE-WGR [WG]

**mirtazapine 15 mg orally disintegrating tablet, 30**

8855C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	17.60	19.05	MIRTANZA ODT [RF]	

**mirtazapine 30 mg tablet, 30**

8513C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.22	18.67	<sup>a</sup> APX-Mirtazapine [TY]	<sup>a</sup> Axit 30 [AF]

NP				<sup>a</sup> Blooms The Chemist Mirtazapine [BG]	<sup>a</sup> MIRTANZA [RF]
				<sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> MIRTAZAPINE-WGR [WG]
				<sup>a</sup> NOUMED MIRTAZAPINE [VO]	
				<sup>a</sup> Avanza [AL]	

**mirtazapine 30 mg orally disintegrating tablet, 30**

8856D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	18.16	19.61	MIRTANZA ODT [RF]	

**mirtazapine 45 mg tablet, 30**

8883M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.57	20.02	<sup>a</sup> APX-Mirtazapine [TY]	<sup>a</sup> Axit 45 [AF]
						<sup>a</sup> Blooms The Chemist Mirtazapine [BG]	<sup>a</sup> MIRTANZA [RF]
						<sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> MIRTAZAPINE-WGR [WG]

**mirtazapine 45 mg orally disintegrating tablet, 30**

8857E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	20.53	21.98	MIRTANZA ODT [RF]	

**■ MIRTAZAPINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mirtazapine 15 mg tablet, 30**

14507M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*19.35	20.80	<sup>a</sup> APX-Mirtazapine [TY]	<sup>a</sup> Axit 15 [AF]
						<sup>a</sup> Blooms The Chemist Mirtazapine [BG]	<sup>a</sup> MIRTANZA [RF]
						<sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> MIRTAZAPINE-WGR [WG]

**mirtazapine 15 mg orally disintegrating tablet, 30**

14369G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*21.75	23.20	MIRTANZA ODT [RF]	

**mirtazapine 30 mg tablet, 30**

14473R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*20.99	22.44	<sup>a</sup> APX-Mirtazapine [TY]	<sup>a</sup> Axit 30 [AF]
						<sup>a</sup> Blooms The Chemist Mirtazapine [BG]	<sup>a</sup> MIRTANZA [RF]
						<sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> MIRTAZAPINE-WGR [WG]
						<sup>a</sup> NOUMED MIRTAZAPINE [VO]	
				<sup>B</sup> 12.02	*33.01	22.44	<sup>a</sup> Avanza [AL]

**mirtazapine 30 mg orally disintegrating tablet, 30**

14370H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*22.87	24.32	MIRTANZA ODT [RF]	

**mirtazapine 45 mg tablet, 30**

14561J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*23.69	25.14	<sup>a</sup> APX-Mirtazapine [TY]	<sup>a</sup> Axit 45 [AF]
						<sup>a</sup> Blooms The Chemist Mirtazapine [BG]	<sup>a</sup> MIRTANZA [RF]
						<sup>a</sup> Mirtazapine Sandoz [SZ]	<sup>a</sup> MIRTAZAPINE-WGR [WG]

**mirtazapine 45 mg orally disintegrating tablet, 30**

14475W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	2	..	*27.61	29.06	MIRTANZA ODT [RF]	

**■ REBOXETINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**reboxetine 4 mg tablet, 60**

8583R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	40.17	31.60	Edronax [PF]

**REBOXETINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**reboxetine 4 mg tablet, 60**

14474T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*66.89	31.60	Edronax [PF]

**VENLAFAXINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**venlafaxine 150 mg modified release capsule, 28**

8302Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.76	19.21	<sup>a</sup> APO-Venlafaxine XR [TX] <sup>a</sup> Enlafax-XR [AF] <sup>a</sup> Venlafaxine generichealth XR [GQ]	<sup>a</sup> Elaxine SR 150 [RW] <sup>a</sup> Sandoz Venlafaxine XR [HX] <sup>a</sup> VENLAFAXINE XR-WGR [WG]
			<sup>b</sup> 2.07	19.83	19.21	<sup>a</sup> Efexor-XR [UJ]	

**venlafaxine 37.5 mg modified release capsule, 28**

8868R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.59	18.04	<sup>a</sup> Efexor-XR [UJ] <sup>a</sup> VENLAFAXINE XR-WGR [WG]	<sup>a</sup> Elaxine SR 37.5 [RW]

**venlafaxine 75 mg modified release capsule, 28**

8301X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.22	18.67	<sup>a</sup> APO-Venlafaxine XR [TX] <sup>a</sup> Enlafax-XR [AF] <sup>a</sup> Venlafaxine generichealth XR [GQ]	<sup>a</sup> Elaxine SR 75 [RW] <sup>a</sup> Sandoz Venlafaxine XR [HX] <sup>a</sup> VENLAFAXINE XR-WGR [WG]
			<sup>b</sup> 2.15	19.37	18.67	<sup>a</sup> Efexor-XR [UJ]	

**VENLAFAXINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**


Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**venlafaxine 150 mg modified release capsule, 28**

14402B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*22.07	23.52	<sup>a</sup> APO-Venlafaxine XR [TX] <sup>a</sup> Enlafax-XR [AF] <sup>a</sup> Venlafaxine generichealth XR [GQ]	<sup>a</sup> Elaxine SR 150 [RW] <sup>a</sup> Sandoz Venlafaxine XR [HX] <sup>a</sup> VENLAFAXINE XR-WGR [WG]

			<sup>B</sup> 4.14	*26.21	23.52	<sup>a</sup> Efexor-XR [UJ]	
<b>venlafaxine 75 mg modified release capsule, 28</b>							
14472Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*20.99	22.44	<sup>a</sup> APO-Venlafaxine XR [TX] <sup>a</sup> Enlafax-XR [AF] <sup>a</sup> Venlafaxine generichealth XR [GQ]	<sup>a</sup> Elaxine SR 75 [RW] <sup>a</sup> Sandoz Venlafaxine XR [HX] <sup>a</sup> VENLAFAXINE XR-WGR [WG]
			<sup>B</sup> 4.30	*25.29	22.44	<sup>a</sup> Efexor-XR [UJ]	

## PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

### ■ GUANFACINE

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**9034**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

#### **Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

#### **Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

#### Authority required (STREAMLINED)

**9031**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

#### Authority required (STREAMLINED)

**8544**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

#### **Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

#### **Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

#### Authority required (STREAMLINED)

**8585**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

**guanfacine 1 mg modified release tablet, 28**

11452R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.30	31.60	Intuniv [TK]

**guanfacine 2 mg modified release tablet, 28**

11451Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.30	31.60	Intuniv [TK]

**guanfacine 3 mg modified release tablet, 28**

11440D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.30	31.60	Intuniv [TK]

**guanfacine 4 mg modified release tablet, 28**

11441E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.30	31.60	Intuniv [TK]

**Centrally acting sympathomimetics****■ ARMODAFINIL**

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

- a psychiatric disorder;
  - a cardiovascular disorder;
  - a history of substance abuse;
  - glaucoma;
  - any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.
- The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. The authority application must be made in writing and must include the following:
- a completed authority prescription form; and
  - a completed Narcolepsy Initial PBS authority application and Supporting information form; and
  - details of the contraindication or intolerance to dexamfetamine sulfate; and
  - either:
    - the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
    - the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
  - The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
  - Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
  - Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
  - Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.
- The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:
- (a) a psychiatric disorder;
  - (b) a cardiovascular disorder;
  - (c) a history of substance abuse;
  - (d) glaucoma;
  - (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Narcolepsy

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with modafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**armodafinil 50 mg tablet, 30**

10922W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*103.57	31.60	Nuvigil [TB]

**armodafinil 150 mg tablet, 30**

10912H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	150.36	31.60	Nuvigil [TB]

**armodafinil 250 mg tablet, 30**

10919Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	244.95	31.60	Nuvigil [TB]

**■ ATOMOXETINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**7876**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority required (STREAMLINED)**

**7890**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**atomoxetine 10 mg capsule, 28**

9092M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.15	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 100 mg capsule, 28**

9290Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	53.55	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 18 mg capsule, 28**

9093N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.15	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 25 mg capsule, 28**

9094P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.15	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 40 mg capsule, 28**

9095Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.15	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 60 mg capsule, 28**

9096R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.15	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 80 mg capsule, 28**

9289X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	53.55	31.60	<sup>a</sup> APO-Atomoxetine [TX]	<sup>a</sup> Atomoxetine Sandoz [SZ]

**■ DEXAMFETAMINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**


Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority required**

Narcolepsy

**dexamfetamine sulfate 5 mg tablet, 100**

1165H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	25.23	26.68	Aspen Pharmacare Australia Pty Ltd [AS]

**■ LISDEXAMFETAMINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 70 mg of PBS-subsidised treatment with this drug.

**Population criteria:**



- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

- the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and
- documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.

#### **lisdexamfetamine dimesilate 30 mg capsule, 30**

10486X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

#### **lisdexamfetamine dimesilate 70 mg capsule, 30**

10492F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

#### **lisdexamfetamine dimesilate 50 mg capsule, 30**

10474G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

#### **lisdexamfetamine dimesilate 20 mg capsule, 30**

11884L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

#### **lisdexamfetamine dimesilate 40 mg capsule, 30**

11898F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

#### **lisdexamfetamine dimesilate 60 mg capsule, 30**

11897E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	100.65	31.60	Vyvanse [TK]

### ■ METHYLPHENIDATE

**Note** Where an increase in maximum quantity is sought, under no circumstances will a quantity beyond 2 times the listed quantity be approved.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

#### **methylphenidate hydrochloride 10 mg tablet, 100**

8839F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.22	31.60	<sup>a</sup> Artige [NM]	<sup>a</sup> Ritalin 10 [NV]

### ■ METHYLPHENIDATE

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

#### **Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

- the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and
- documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.

**methylphenidate hydrochloride 40 mg modified release capsule, 30**

2283E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	55.13	31.60	<sup>a</sup> Ritalin LA [NV]	<sup>a</sup> Rubifen LA [AE]

▪ **METHYLPHENIDATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**methylphenidate hydrochloride 36 mg modified release tablet, 30**

2388Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.59	31.60	<sup>a</sup> Concerta [JC]	<sup>a</sup> METHYLPHENIDATE-TEVA XR [TB]
						<sup>a</sup> Methylphenidate XR ARX [XT]	

▪ **METHYLPHENIDATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.

**methylphenidate hydrochloride 10 mg modified release capsule, 30**

3440C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.04	31.60	<sup>a</sup> Ritalin LA [NV]	<sup>a</sup> Rubifen LA [AE]

**methylphenidate hydrochloride 20 mg modified release capsule, 30**

2276T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	46.27	31.60	<sup>a</sup> Ritalin LA [NV]	<sup>a</sup> Rubifen LA [AE]

**methylphenidate hydrochloride 30 mg modified release capsule, 30**

2280B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.87	31.60	<sup>a</sup> Ritalin LA [NV]	<sup>a</sup> Rubifen LA [AE]

**methylphenidate hydrochloride 60 mg modified release capsule, 30**

12116Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	67.46	31.60	<sup>a</sup> Ritalin LA [NV]	<sup>a</sup> Rubifen LA [AE]

**■ METHYLPHENIDATE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**methylphenidate hydrochloride 18 mg modified release tablet, 30**

2387P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.25	31.60	<sup>a</sup> Concerta [JC]	<sup>a</sup> METHYLPHENIDATE-TEVA XR [TB]
						<sup>a</sup> Methylphenidate XR ARX [XT]	

**methylphenidate hydrochloride 27 mg modified release tablet, 30**

2172H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	55.91	31.60	<sup>a</sup> Concerta [JC]	<sup>a</sup> METHYLPHENIDATE-TEVA XR [TB]
						<sup>a</sup> Methylphenidate XR ARX [XT]	

**methylphenidate hydrochloride 54 mg modified release tablet, 30**

2432B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	67.70	31.60	<sup>a</sup> Concerta [JC]	<sup>a</sup> METHYLPHENIDATE-TEVA XR [TB]
						<sup>a</sup> Methylphenidate XR ARX [XT]	

**■ MODAFINIL**

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

**Authority required**

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

- (a) a psychiatric disorder;
  - (b) a cardiovascular disorder;
  - (c) a history of substance abuse;
  - (d) glaucoma;
  - (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.
- The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. The authority application must be made in writing and must include the following:
- (a) a completed authority prescription form; and
  - (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
  - (c) details of the contraindication or intolerance to dexamfetamine sulfate; and
  - (d) either:
    - (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
    - (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.
- The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).

Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**

- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
  - Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.
- The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:
- (a) a psychiatric disorder;
  - (b) a cardiovascular disorder;
  - (c) a history of substance abuse;
  - (d) glaucoma;
  - (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Narcolepsy

Treatment Phase: Continuing or change of treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with armodafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **modafinil 100 mg tablet, 60**

8816B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.99	31.60	<sup>a</sup> APO-Modafinil [TX] <sup>a</sup> Modafinil GH [GQ] <sup>a</sup> Modafinil Viatris [AL]	<sup>a</sup> Modafin [RW] <sup>a</sup> Modafinil Sandoz [SZ] <sup>a</sup> MODAFINIL-WGR [WG]
			<sup>B</sup> 10.80	*144.79	31.60	<sup>a</sup> Modavigil [TB]	

## **ANTI-DEMENTIA DRUGS**

### *Anticholinesterases*

#### ▪ **DONEPEZIL**

##### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**13938**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

#### **Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

### **donepezil hydrochloride 10 mg tablet, 28**

2479L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.33	20.78	<sup>a</sup> APO-Donepezil [TX] <sup>a</sup> Aridon 10 [RW] <sup>a</sup> Donepezil GH [HQ] <sup>a</sup> DONEPEZIL-WGR [WG]	<sup>a</sup> Arazil [AF] <sup>a</sup> Aridon APN 10 [RF] <sup>a</sup> Donepezil Sandoz [SZ]
			<sup>B</sup> 6.09	25.42	20.78	<sup>a</sup> Aricept [PF]	

### **donepezil hydrochloride 5 mg tablet, 28**

2532G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	19.33	20.78	<sup>a</sup> APO-Donepezil [TX] <sup>a</sup> Aridon 5 [RW] <sup>a</sup> Donepezil GH [HQ]	<sup>a</sup> Arazil [AF] <sup>a</sup> Aridon APN 5 [RF] <sup>a</sup> Donepezil Sandoz [SZ]

<sup>a</sup> DONEPEZIL-WGR [WG]<sup>B</sup>6.13 25.46 20.78 <sup>a</sup> Aricept [PF]

## ■ DONEPEZIL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

### Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

### Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

### Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

### Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

## donepezil hydrochloride 10 mg tablet, 28

8496E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	19.33	20.78	<sup>a</sup> APO-Donepezil [TX] <sup>a</sup> Aridon 10 [RW] <sup>a</sup> Donepezil GH [HQ] <sup>a</sup> DONEPEZIL-WGR [WG]	<sup>a</sup> Arazil [AF] <sup>a</sup> Aridon APN 10 [RF] <sup>a</sup> Donepezil Sandoz [SZ]
			<sup>B</sup> 6.09	25.42	20.78	<sup>a</sup> Aricept [PF]	

## donepezil hydrochloride 5 mg tablet, 28

8495D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	19.33	20.78	<sup>a</sup> APO-Donepezil [TX] <sup>a</sup> Aridon 5 [RW] <sup>a</sup> Donepezil GH [HQ] <sup>a</sup> DONEPEZIL-WGR [WG]	<sup>a</sup> Arazil [AF] <sup>a</sup> Aridon APN 5 [RF] <sup>a</sup> Donepezil Sandoz [SZ]
			<sup>B</sup> 6.13	25.46	20.78	<sup>a</sup> Aricept [PF]	

## ■ GALANTAMINE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**13938**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

### Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**

- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.
- Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.
- Clinically meaningful response to treatment is demonstrated in the following areas:
- Patient's quality of life including but not limited to level of independence and happiness;
- Patient's cognitive function including but not limited to memory, recognition and interest in environment;
- Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 16 mg modified release capsule, 28**

2537M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.22	31.60	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Gamine XR [RW]	<sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]

**galantamine 24 mg modified release capsule, 28**

2531F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.35	31.60	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Gamine XR [RW]	<sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]

**galantamine 8 mg modified release capsule, 28**

2463P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.34	31.60	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Gamine XR [RW]	<sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]

**■ GALANTAMINE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**galantamine 16 mg modified release capsule, 28**

8771P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	40.22	31.60	<sup>a</sup> APO-Galantamine MR [TX]	<sup>a</sup> Galantyl [AF]

<sup>a</sup> Gamine XR [RW]<sup>a</sup> Reminyl [JC]**galantamine 24 mg modified release capsule, 28**

8772Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	45.35	31.60	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Gamine XR [RW]	<sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]

**galantamine 8 mg modified release capsule, 28**

8770N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	35.34	31.60	<sup>a</sup> APO-Galantamine MR [TX] <sup>a</sup> Gamine XR [RW]	<sup>a</sup> Galantyl [AF] <sup>a</sup> Reminyl [JC]

**■ RIVASTIGMINE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****13938**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
  - Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
- Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**rivastigmine 13.3 mg/24 hours patch, 30**

10538P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 15 [NV]

**rivastigmine 1.5 mg capsule, 56**

2475G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 3 mg capsule, 56**

2493F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 4.5 mg capsule, 56**

2494G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 6 mg capsule, 56**

2526Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 9.5 mg/24 hours patch, 30**

2551G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 10 [NV]

**rivastigmine 4.6 mg/24 hours patch, 30**

2477J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 5 [NV]

**■ RIVASTIGMINE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**



Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**rivastigmine 13.3 mg/24 hours patch, 30**

10541T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 15 [NV]

**rivastigmine 1.5 mg capsule, 56**

8497F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 3 mg capsule, 56**

8498G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 4.5 mg capsule, 56**

8499H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 6 mg capsule, 56**

8500J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	64.82	31.60	Exelon [NV]

**rivastigmine 9.5 mg/24 hours patch, 30**

9162F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 10 [NV]

**rivastigmine 4.6 mg/24 hours patch, 30**

9161E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	82.96	31.60	Exelon Patch 5 [NV]

*Other anti-dementia drugs*

▪ **MEMANTINE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****13966**

Moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**memantine hydrochloride 10 mg tablet, 56**

2492E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	43.66	31.60	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memanxa [RW]

**memantine hydrochloride 20 mg tablet, 28**

2513G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	43.66	31.60	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU]

**MEMANTINE**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**memantine hydrochloride 10 mg tablet, 56**

1956Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.66	31.60	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU] <sup>a</sup> Memanxa [RW]

**memantine hydrochloride 20 mg tablet, 28**

9306T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.66	31.60	<sup>a</sup> APO-Memantine [TX] <sup>a</sup> Memantine generichealth [GQ]	<sup>a</sup> Ebixa [LU]

## OTHER NERVOUS SYSTEM DRUGS

### PARASYMPATHOMIMETICS

#### Anticholinesterases

#### ■ PYRIDOSTIGMINE

**pyridostigmine bromide 10 mg tablet, 50**

2724J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*26.37	27.82	Mestinon [IL]

**pyridostigmine bromide 180 mg modified release tablet, 50**

2608G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*95.49	31.60	Mestinon Timespan [IL]

**pyridostigmine bromide 60 mg tablet, 150**

1959D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	50.74	31.60	Mestinon [IL]

#### ■ PYRIDOSTIGMINE

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pyridostigmine bromide 10 mg tablet, 50**

14392L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*39.27	31.60	Mestinon [IL]

**pyridostigmine bromide 180 mg modified release tablet, 50**

14462E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*180.71	31.60	Mestinon Timespan [IL]

**pyridostigmine bromide 60 mg tablet, 150**

14529Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*88.03	31.60	Mestinon [IL]

#### Choline esters

#### ■ BETHANECHOL

**bethanechol chloride 10 mg tablet, 100**

1062X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	31.30	31.60	Uro-Carb [YN]

## DRUGS USED IN ADDICTIVE DISORDERS

### Drugs used in nicotine dependence

#### ■ BUPROPION

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****6881**

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**bupropion hydrochloride 150 mg modified release tablet, 90**

8710K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	170.49	31.60	Zyban [AS]

**■ BUPROPION**

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****6882**

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**bupropion hydrochloride 150 mg modified release tablet, 30**

8465M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	64.90	31.60	Zyban [AS]

**■ NICOTINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**nicotine 14 mg/24 hours patch, 28**

5572G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	Nicotinell Step 2 [UI]

**nicotine 21 mg/24 hours patch, 28**

3414Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	Nicotinell Step 1 [UI]

**nicotine 21 mg/24 hours patch, 28**

5465P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	Nicabate P [GJ]

**nicotine 7 mg/24 hours patch, 28**

5573H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	Nicotinell Step 3 [UI]

**nicotine 25 mg/16 hours patch, 28**

10076H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	nicorette 16hr Invisipatch [JT]

**■ NICOTINE**

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**nicotine 21 mg/24 hours patch, 28**

5571F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	51.34	31.60	Nicotinell Step 1 [UI]

**■ VARENICLINE**

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6885**

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**varenicline 1 mg tablet, 56**

5469W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	70.94	31.60	<sup>a</sup> Champix [PF]	<sup>a</sup> PHARMACOR VARENICLINE [CR]
						<sup>a</sup> VARENAPIX [TX]	<sup>a</sup> Varenicline Sandoz [SZ]
						<sup>a</sup> Varenicline Viatris [AF]	

**■ VARENICLINE**

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**7483**

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received treatment with this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

### varenicline 1 mg tablet, 56

9129L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*129.17	31.60	<sup>a</sup> Champix [PF]	<sup>a</sup> PHARMACOR VARENICLINE [CR]
						<sup>a</sup> VARENAPIX [TX]	<sup>a</sup> Varenicline Sandoz [SZ]
						<sup>a</sup> Varenicline Viatris [AF]	

### ■ VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**6871**

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

#### **Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

#### **Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

### varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53

9128K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	..	..	62.22	31.60	<sup>a</sup> Champix [PF]	<sup>a</sup> PHARMACOR VARENICLINE [CR]
						<sup>a</sup> VARENAPIX [TX]	<sup>a</sup> Varenicline Sandoz [SZ]
						<sup>a</sup> Varenicline Viatris [AF]	

### *Drugs used in alcohol dependence*

### ■ ACAMPROSATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**5366**

Alcohol dependence

#### **Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

### acamprosate calcium 333 mg enteric tablet, 180

8357W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	79.25	31.60	<sup>a</sup> ACAMPROSATE VIATRIS [MQ]	<sup>a</sup> ACAMPROSATE-WGR [WG]
						<sup>a</sup> APO-Acamprosate [TX]	<sup>a</sup> Campral [AF]

### ■ NALTREXONE

**Caution** Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**13967**

Alcohol dependence

#### **Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.

**naltrexone hydrochloride 50 mg tablet, 30**

8370M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	1	..	95.91	31.60	<sup>a</sup> ARX-NALTREXONE [XT]	<sup>a</sup> Naltrexone GH [GQ]

**OTHER NERVOUS SYSTEM DRUGS***Other nervous system drugs***■ AMIFAMPRIDINE**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Lambert-Eaton myasthenic syndrome (LEMS)

**Clinical criteria:**

- The condition must not be any of: (i) myasthenia gravis, (ii) Guillain-Barre syndrome.

**Treatment criteria:**

- Must be treated by a prescriber type identifying as at least one of the following: (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists.

**amifampidine 10 mg tablet, 100**

13032X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4461.39	31.60	Ruzurgi [OJ]

**■ RILUZOLE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

**riluzole 50 mg/10 mL oral liquid, 300 mL**

14429K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*402.63	31.60	Teglutik [CS]

**riluzole 50 mg tablet, 56**

14393M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*264.29	31.60	<sup>a</sup> Pharmacor Riluzole [CR]	<sup>a</sup> Rilutek [SW]
						<sup>a</sup> Riluzole Sandoz [SZ]	

**■ RILUZOLE****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

**riluzole 50 mg/10 mL oral liquid, 300 mL**

11662T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*205.55	31.60	Teglutik [CS]

**riluzole 50 mg tablet, 56**

8664B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	136.37	31.60	<sup>a</sup> Pharmacor Riluzole [CR] <sup>a</sup> Riluzole Sandoz [SZ]	<sup>a</sup> Rilutek [SW]

■ **TAFAMIDIS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Transthyretin amyloid cardiomyopathy

Treatment Phase: First PBS-subsidised prescription for this drug

**Clinical criteria:**

- The condition must have documented evidence of transthyretin precursor protein present, **AND**
- Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR
- Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement, **AND**
- Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR
- Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug, **AND**
- Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m<sup>2</sup>.

**Treatment criteria:**

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- a completed authority prescription form; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of clinical findings to establish the diagnosis:

In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below:

Confirm the following has been completed:

- amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR
- bone scintigraphy with grade 2-3 finding **AND**
- Confirm that there are negative results for monoclonal protein on each of the following three tests:
  - serum immunofixation (also known as protein electrophoresis)
  - urine immunofixation
  - serum free light chains blood test

State which of (1) to (3) above has been completed, as well as the:

- date of the finding,
- imaging/pathology report number/code that links the finding to the patient,
- name of the amyloid expert centre in this authority application (if applicable).

For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that:

- imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and
- that the imaging report is stored in the patient's medical records.

State the date that the imaging was performed and the thickness (in mm) in this authority application.

Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following:



(i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The Australian Amyloid Network provides a list of clinic centres that manage amyloidosis. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing. For the purposes of this restriction, these providers are considered to be amyloid expert centres.

#### **Authority required**

Transthyretin amyloid cardiomyopathy

Treatment Phase: Second and subsequent PBS-subsidised prescriptions for this drug

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m<sup>2</sup>, **AND**
- The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure, **AND**
- The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).

If 'no', continued PBS subsidy is available.

If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent.

Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.

If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **tafamidis 61 mg capsule, 30**

14100D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10022.60	31.60	Vyndamax [PF]

### ▪ **TETRABENAZINE**

#### **Note Continuing Therapy Only:**


For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**5340**

Hyperkinetic extrapyramidal disorders

### **tetrabenazine 25 mg tablet, 112**

1330B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	236.48	31.60	<sup>a</sup> iNova Pharmaceuticals (Australia) Pty Ltd [IL]	<sup>a</sup> Tetrabenazine SUN [RA]

### ▪ **TETRABENAZINE**

#### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### **Authority required (STREAMLINED)**

**15673**

Hyperkinetic extrapyramidal disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**tetrabenazine 25 mg tablet, 112**

14390J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*464.49	31.60	<sup>a</sup> iNova Pharmaceuticals (Australia) Pty Ltd [IL]	<sup>a</sup> Tetrabenazine SUN [RA]

## ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ANTIPROTOZOALS

### AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

*Other agents against amoebiasis and other protozoal diseases*

#### ATOVAQUONE

**Authority required (STREAMLINED)**

**5609**

Mild to moderate *Pneumocystis carinii* pneumonia

**Population criteria:**

- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

8300W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	..	..	982.48	31.60	<sup>a</sup> ATOVACUE [JM]	<sup>a</sup> Wellvone [AS]

### ANTIMALARIALS

*Biguanides*

#### ATOVAQUONE + PROGUANIL

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected *Plasmodium falciparum* malaria

**Population criteria:**

- Patient must be aged 3 years or older.

**Clinical criteria:**

- The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

9439T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	68.53	31.60	<sup>a</sup> AtovaquoPro Lupin 250/100 [GQ]	<sup>a</sup> Malarone [GK]

*Methanolquinolines*

#### QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.

**Authority required (STREAMLINED)**

**5633**

Malaria

**quinine sulfate dihydrate 300 mg tablet, 50**

1975Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	22.28	23.73	Quinate [RW]

*Artemisinin and derivatives, combinations*

#### ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected *Plasmodium falciparum* malaria

**Clinical criteria:**

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

**artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18**

5296R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	101.92	31.60	Riamet 20mg/120mg Dispersible [NV]

## ■ ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

Confirmed or suspected Plasmodium falciparum malaria

**artemether 20 mg + lumefantrine 120 mg tablet, 24**

9498X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	65.44	31.60	Riamet [NV]

## ■ ANTHELMINTICS

## ANTITREMATODALS

*Quinoline derivatives and related substances*

## ■ PRAZICUANTEL

**Authority required (STREAMLINED)**

**5659**

Schistosomiasis

**praziquantel 600 mg tablet, 8**

9447F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	32.38	31.60	Biltricide [BN]

NP

## ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

## ■ ALBENDAZOLE

**Authority required (STREAMLINED)**

**5607**

Hydatid disease

**Clinical criteria:**

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

**albendazole 400 mg tablet, 60**

8459F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	116.31	31.60	Eskazole [AS]

## ■ ALBENDAZOLE

**Authority required (STREAMLINED)**

**5680**

Tapeworm infestation

**albendazole 200 mg tablet, 6**

8503M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	29.19	30.64	Zentel [AS]

NP

## ■ ALBENDAZOLE

**Authority required (STREAMLINED)**

**5817**

Whipworm infestation

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required (STREAMLINED)**

**5712**

Strongyloidiasis

**Authority required (STREAMLINED)**

**5797**

Hookworm infestation

**albendazole 200 mg tablet, 6**

9047E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	29.19	30.64	Zentel [AS]

NP

*Tetrahydropyrimidine derivatives*

## ■ PYRANTEL

## pyrantel 125 mg tablet, 6

3047J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.05	19.50	Anthel 125 [AF]

## pyrantel 250 mg tablet, 6

3048K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.45	23.90	Anthel 250 [AF]

## Avermectines

## ■ IVERMECTIN

Authority required (STREAMLINED)

4319

Onchocerciasis

## ivermectin 3 mg tablet, 4

8359Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.04	31.60	Stromectol [MK]

## ■ IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Authority required (STREAMLINED)

4566

Human sarcoptic scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.

Authority required (STREAMLINED)

12604

Human sarcoptic scabies

**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander, **AND**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

## ivermectin 3 mg tablet, 4

2868Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*48.63	31.60	Stromectol [MK]

## ■ ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

## ECTOPARASITICIDES, INCL. SCABICIDES

Pyrethrines, incl. synthetic compounds

## ■ PERMETHRIN

### permethrin 5% cream, 30 g

3054R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	20.78	22.23	Lyclear [UI]

### permethrin 5% cream, 60 g

14259L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	61.84	31.60	Permethrin Cream 5% w/w (Encube Ethicals, USA) [RQ]

## ■ RESPIRATORY SYSTEM

## ■ NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

#### Other nasal preparations

## ■ MUPIROCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**6647**

Staphylococcus aureus infection

#### Clinical criteria:

- Patient must have nasal colonisation with the bacteria.

#### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

### mupirocin 2% ointment, 5 g

11822F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	26.98	28.43	Mupirocin Nasal (Medsurge) [DZ]

### mupirocin 2% ointment, 3 g

9440W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	23.45	24.90	Bactroban [GK]

## ■ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### ADRENERGICS, INHALANTS

#### Selective beta-2-adrenoreceptor agonists

## ■ FORMOTEROL

#### Restricted benefit

Asthma

#### Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

### formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules

8136F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	30.45	31.60	Foradile [SZ]

### formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

8240Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	29.95	31.40	Oxis Turbuhaler [AP]

### formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

8239P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	24.43	25.88	Oxis Turbuhaler [AP]

## ■ FORMOTEROL

#### Restricted benefit

Asthma

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

14419X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*47.45	31.60	Foradile [SZ]

**formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

14517C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*46.45	31.60	Oxis Turbuhaler [AP]

**formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

14547P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*35.41	31.60	Oxis Turbuhaler [AP]

**■ INDACATEROL**

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**indacaterol 150 microgram powder for inhalation, 30 capsules**

5134F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.37	31.60	Onbrez [NV]

**indacaterol 300 microgram powder for inhalation, 30 capsules**

5137J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.37	31.60	Onbrez [NV]

**■ INDACATEROL**

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**indacaterol 150 microgram powder for inhalation, 30 capsules**

14334K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*105.29	31.60	Onbrez [NV]

**indacaterol 300 microgram powder for inhalation, 30 capsules**

14368F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*105.29	31.60	Onbrez [NV]

**■ SALBUTAMOL****salbutamol 100 microgram/actuation inhalation, 200 actuations**

12109H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*25.13	26.58	<sup>a</sup> Zempreon CFC-Free with dose counter [AL]
			<sup>B</sup> 0.92	*26.05	26.58	<sup>a</sup> Asmol CFC-Free with dose counter [AF]
			<sup>B</sup> 6.00	*31.13	26.58	<sup>a</sup> Ventolin CFC-Free with dose counter [GK]

## ■ SALBUTAMOL

### Restricted benefit

Bronchospasm

### Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

### salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations

8354Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*41.45	31.60	Airomir Autohaler [IL]

## ■ SALBUTAMOL

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.09	25.54	<sup>a</sup> Salbutamol Cipla [LR]

### salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2001H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*24.21	25.66	<sup>a</sup> Salbutamol Cipla [LR]

### salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11130T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	<sup>B</sup> 5.04	*28.11	24.52	<sup>a</sup> Ventolin Nebules [GK]

### salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11095Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	<sup>B</sup> 5.01	*28.50	24.94	<sup>a</sup> Ventolin Nebules [GK]

## ■ SALMETEROL

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

### salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8141L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	30.45	31.60	Serevent Accuhaler [GK]

## ■ SALMETEROL

### Restricted benefit

Asthma

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

### salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14328D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡2	5	..	*47.45	31.60	Serevent Accuhaler [GK]

## ■ TERBUTALINE

### Authority required (STREAMLINED)

**9828**

Bronchospasm

### **Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; OR
- Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

### **terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations**

12267P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*28.13	29.58	Bricanyl Turbuhaler [AP]

*Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics*

## ■ BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

### Authority required (STREAMLINED)

**15469**

Asthma

### **Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

### **Population criteria:**

- Patient must be at least 18 years of age.

### **beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

12183F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	37.47	31.60	Fostair [EU]

## ■ BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

### Authority required (STREAMLINED)

**15599**

Asthma

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

### **Population criteria:**

- Patient must be at least 18 years of age.



**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14376P	±2	5	..	*61.49	31.60	Fostair [EU]

NP

**■ BECLOMETASONE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority required (STREAMLINED)****11057**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13205B	±1	5	..	48.00	31.60	Fostair 200/6 [EU]

NP

**■ BECLOMETASONE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority required (STREAMLINED)****15656**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14538E	±2	5	..	*82.55	31.60	Fostair 200/6 [EU]

NP

**■ BUDESONIDE + FORMOTEROL**

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)****10482**

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

**Population criteria:**

- Patient must be aged 12 years or over.
- Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12042T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	2	..	*42.29	31.60	<sup>a</sup> Rilast RAPIHALER 100/3 [XT]
			<sup>B</sup> 4.96	*47.25	31.60	<sup>a</sup> Symbicort Rapihaler 100/3 [AP]

**■ BUDESONIDE + FORMOTEROL**

**Note** Patient must be aged 12 years or over.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)****10464**

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
  - Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).
- Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

14166N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	2	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

**■ BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)****10464**

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
  - Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).
- Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12029D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	37.47	31.60	<sup>a</sup> DuoResp Spiromax [EV]

**■ BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)****10464**

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
  - Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).
- Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12041R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	37.47	31.60	<sup>a</sup> Rilast TURBUHALER 200/6 [XT]

<sup>B</sup>4.00      41.47      31.60      <sup>a</sup> Symbicort Turbuhaler 200/6  
[AP]

## ■ BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### Authority required (STREAMLINED)

**4380**

Asthma

#### Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

#### Population criteria:

- Patient must be aged 12 years or over.

### budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8796Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	40.97	31.60	Symbicort Turbuhaler 100/6 [AP]

## ■ BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### Authority required (STREAMLINED)

**4397**

Asthma

#### Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

#### Population criteria:

- Patient must be aged 12 years or over.

### budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

10015D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*42.29	31.60	<sup>a</sup> Rilast RAPIHALER 100/3 [XT]
			<sup>B</sup> 4.96	*47.25	31.60	<sup>a</sup> Symbicort Rapihaler 100/3 [AP]

## ■ BUDESONIDE + FORMOTEROL

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### Authority required (STREAMLINED)

**10538**

Asthma

#### Clinical criteria:

- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

12082X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*60.91	31.60	<sup>a</sup> Rilast RAPIHALER 200/6 [XT]
			<sup>B</sup> 4.96	*65.87	31.60	<sup>a</sup> Symbicort Rapihaler 200/6 [AP]

**■ BUDESONIDE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****10538**

Asthma

**Clinical criteria:**

- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12089G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*42.29	31.60	<sup>a</sup> Rilast RAPIHALER 100/3 [XT]
			<sup>B</sup> 4.96	*47.25	31.60	<sup>a</sup> Symbicort Rapihaler 100/3 [AP]

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12101X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	40.97	31.60	Symbicort Turbuhaler 100/6 [AP]

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12093L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	37.47	31.60	<sup>a</sup> DuoResp Spiromax [EV]	<sup>a</sup> Rilast TURBUHALER 200/6 [XT]
			<sup>B</sup> 4.00	41.47	31.60	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]	

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

14159F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

**■ BUDESONIDE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15577**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

14535B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±4	5	..	*71.11	31.60	<sup>a</sup> Rilast RAPIHALER 100/3 [XT]
			<sup>B</sup> 9.92	*81.03	31.60	<sup>a</sup> Symbicort Rapihaler 100/3 [AP]

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14437W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*68.49	31.60	Symbicort Turbuhaler 100/6 [AP]

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14365C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*61.49	31.60	<sup>a</sup> DuoResp Spiromax [EV]	<sup>a</sup> Rilast TURBUHALER 200/6 [XT]
			<sup>B</sup> 8.00	*69.49	31.60	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]	

**■ BUDESONIDE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15755**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14440B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*68.49	31.60	Symbicort Turbuhaler 100/6 [AP]

**■ BUDESONIDE + FORMOTEROL**

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15577**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

14436T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±4	5	..	*108.35	31.60	<sup>a</sup> Rilast RAPIHALER 200/6 [XT]
			<sup>B</sup> 10.16	*118.51	31.60	<sup>a</sup> Symbicort Rapihaler 200/6 [AP]

**■ BUDESONIDE + FORMOTEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15702**

Asthma


**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

14467K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*71.11	31.60	<sup>a</sup> Rilast RAPIHALER 100/3 [XT]
			<sup>B</sup> 9.92	*81.03	31.60	<sup>a</sup> Symbicort Rapihaler 100/3 [AP]

**■ BUDESONIDE + FORMOTEROL**

**Note** Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.


**Authority required (STREAMLINED)****7970**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

14151T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*37.49	31.60	Bufomix Easyhaler 200/6 [OX]

**■ BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**7970**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

11273H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	37.47	31.60	<sup>a</sup> DuoResp Spiromax [EV]

▪ **BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**7970**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8625Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	37.47	31.60	<sup>a</sup> Rilast TURBUHALER 200/6 [XT]
			<sup>B</sup> 4.00	41.47	31.60	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]

▪ **BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15680**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14434Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*61.49	31.60	<sup>a</sup> DuoResp Spiromax [EV]

**■ BUDESONIDE + FORMOTEROL**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15680**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14439Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*61.49	31.60	<sup>a</sup> Rilast TURBUHALER 200/6 [XT]
			<sup>B</sup> 8.00	*69.49	31.60	<sup>a</sup> Symbicort Turbuhaler 200/6 [AP]

**■ BUDESONIDE + FORMOTEROL**
**Authority required (STREAMLINED)**

**4404**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**10121**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.



**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.  
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

10018G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*60.91	31.60	<sup>a</sup> Rilast RAPIHALER 200/6 [XT]
			<sup>B</sup> 4.96	*65.87	31.60	<sup>a</sup> Symbicort Rapihaler 200/6 [AP]

#### ■ BUDESONIDE + FORMOTEROL

##### Authority required (STREAMLINED)

**15615**

Asthma

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

##### **Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

##### Authority required (STREAMLINED)

**15548**

Chronic obstructive pulmonary disease (COPD)

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

14468L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*108.35	31.60	<sup>a</sup> Rilast RAPIHALER 200/6 [XT]
			<sup>B</sup> 10.16	*118.51	31.60	<sup>a</sup> Symbicort Rapihaler 200/6 [AP]

#### ■ BUDESONIDE + FORMOTEROL

**Note** For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

**Note** Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

##### Authority required (STREAMLINED)

**7979**

Asthma

##### **Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** Patient must be aged 18 years or older.

**Note** Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

## **Authority required (STREAMLINED)**

**10121**

Chronic obstructive pulmonary disease (COPD)

### **Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

## **budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

13258T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*60.93	31.60	<sup>a</sup> Bufomix Easyhaler 400/12 [OX]	<sup>a</sup> DuoResp Spiromax [EV]
						<sup>a</sup> Rilast TURBUHALER 400/12 [XT]	
			<sup>B</sup> 4.00	*64.93	31.60	<sup>a</sup> Symbicort TURBUHALER 400/12 [AP]	

## **budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations**

11301T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	60.92	31.60	<sup>a</sup> DuoResp Spiromax [EV]

## **■ BUDESONIDE + FORMOTEROL**

**Note** For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

**Note** Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

## **Authority required (STREAMLINED)**

**15617**

Asthma

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** Patient must be aged 18 years or older.

**Note** Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

## **Authority required (STREAMLINED)**

**15548**

Chronic obstructive pulmonary disease (COPD)

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

14398T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*108.39	31.60	<sup>a</sup> Bufomix Easyhaler 400/12 [OX]	<sup>a</sup> DuoResp Spiromax [EV]
						<sup>a</sup> Rilast TURBUHALER 400/12 [XT]	
			<sup>B</sup> 8.12	*116.51	31.60	<sup>a</sup> Symbicort TURBUHALER 400/12 [AP]	

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations**

14435R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*108.39	31.60	<sup>a</sup> DuoResp Spiromax [EV]

**■ FLUTICASONE FUROATE + VILANTEROL**

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****4731**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11129R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	70.97	31.60	Breo Ellipta 200/25 [GK]

**■ FLUTICASONE FUROATE + VILANTEROL**

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15692**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

14345B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*129.23	31.60	Breo Ellipta 200/25 [GK]

**■ FLUTICASONE FUROATE + VILANTEROL****Authority required (STREAMLINED)****4711**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****10121**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11124L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	56.24	31.60	Breo Ellipta 100/25 [GK]

**■ FLUTICASONE FUROATE + VILANTEROL****Authority required (STREAMLINED)****15546**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15548**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

14379T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*99.03	31.60	Breo Ellipta 100/25 [GK]

**■ FLUTICASONE PROPIONATE + FORMOTEROL**

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**4395**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

2827T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	39.28	31.60	flutiform 50/5 [MF]

**fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

10007Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	39.85	31.60	flutiform 125/5 [MF]

**fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations**

10008R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	51.57	31.60	flutiform 250/10 [MF]

▪ **FLUTICASONE PROPIONATE + FORMOTEROL**

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15635**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

14411L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*65.11	31.60	flutiform 50/5 [MF]

**fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

14343X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*66.25	31.60	flutiform 125/5 [MF]

**fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations**

14344Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*89.69	31.60	flutiform 250/10 [MF]

▪ **FLUTICASONE PROPIONATE + SALMETEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**4930**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

8518H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	42.57	31.60	<sup>a</sup> Evocair MDI [AF]	<sup>a</sup> Fluticasone + Salmeterol Cipla 125/25 [LR]
						<sup>a</sup> Pavtide [TX]	<sup>a</sup> SalplusF Inhaler 125/25 [SZ]
			<sup>B</sup> 4.00	46.57	31.60	<sup>a</sup> Seretide MDI 125/25 [GK]	

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

8517G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	43.93	31.60	<sup>a</sup> PAVTIDE MDI 50/25 [TX]
			<sup>B</sup> 4.00	47.93	31.60	<sup>a</sup> Seretide MDI 50/25 [GK]

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8430Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	43.93	31.60	<sup>a</sup> PAVTIDE ACCUHALER 100/50 [TX]
			<sup>B</sup> 4.00	47.93	31.60	<sup>a</sup> Seretide Accuhaler 100/50 [GK]

■ **FLUTICASONE PROPIONATE + SALMETEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15138**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

8431R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	42.57	31.60	<sup>a</sup> Fluticasone Salmeterol Cipla 250/50 [LR]	<sup>a</sup> PAVTIDE ACCUHALER 250/50 [TX]
						<sup>a</sup> Salfumix Easyhaler 250/50 [OX]	<sup>a</sup> SalplusF DPI 250/50 [SZ]
			<sup>B</sup> 4.00	46.57	31.60	<sup>a</sup> Seretide Accuhaler 250/50 [GK]	

■ **FLUTICASONE PROPIONATE + SALMETEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15604**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

14544L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*71.69	31.60	<sup>a</sup> Evocair MDI [AF]	<sup>a</sup> Fluticasone + Salmeterol Cipla 125/25 [LR]
						<sup>a</sup> Pavtide [TX]	<sup>a</sup> SalplusF Inhaler 125/25 [SZ]
						<sup>B</sup> 8.00	<sup>a</sup> Seretide MDI 125/25 [GK]

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

14414P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*74.41	31.60	<sup>a</sup> PAVTIDE MDI 50/25 [TX]	
						<sup>B</sup> 8.00	<sup>a</sup> Seretide MDI 50/25 [GK]

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

14413N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*74.41	31.60	<sup>a</sup> PAVTIDE ACCUHALER 100/50 [TX]	
						<sup>B</sup> 8.00	<sup>a</sup> Seretide Accuhaler 100/50 [GK]

**■ FLUTICASONE PROPIONATE + SALMETEROL**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15693**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

14449L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*71.69	31.60	<sup>a</sup> Fluticasone Salmeterol Cipla 250/50 [LR]	<sup>a</sup> PAVTIDE ACCUHALER 250/50 [TX]
						<sup>a</sup> Salfumix Easyhaler 250/50 [OX]	<sup>a</sup> SalplusF DPI 250/50 [SZ]
						<sup>B</sup> 8.00	<sup>a</sup> Seretide Accuhaler 250/50 [GK]

**■ FLUTICASONE PROPIONATE + SALMETEROL****Authority required (STREAMLINED)****15118**

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****10121**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8432T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	52.87	31.60	<sup>a</sup> Fluticasone Salmeterol Cipla 500/50 [LR]	<sup>a</sup> PAVTIDE ACCUHALER 500/50 [TX]
						<sup>a</sup> Salflumix Easyhaler 500/50 [OX]	<sup>a</sup> SalplusF DPI 500/50 [SZ]
				<sup>B</sup> 4.00	56.87	31.60	<sup>a</sup> Seretide Accuhaler 500/50 [GK]

### ■ FLUTICASONE PROPIONATE + SALMETEROL

#### Authority required (STREAMLINED)

**4930**

Asthma

#### **Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

#### **Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### Authority required (STREAMLINED)

**10121**

Chronic obstructive pulmonary disease (COPD)

#### **Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8519J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	52.87	31.60	<sup>a</sup> Evocair MDI [AF]	<sup>a</sup> Fluticasone + Salmeterol Cipla 250/25 [LR]
						<sup>a</sup> Pavtide [TX]	<sup>a</sup> SalplusF Inhaler 250/25 [SZ]
				<sup>B</sup> 4.00	56.87	31.60	<sup>a</sup> Seretide MDI 250/25 [GK]

### ■ FLUTICASONE PROPIONATE + SALMETEROL

#### Authority required (STREAMLINED)

**15715**

Asthma

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

#### **Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### Authority required (STREAMLINED)

**15548**

Chronic obstructive pulmonary disease (COPD)

#### **Clinical criteria:**



- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

#### fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

14311F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*92.29	31.60	<sup>a</sup> Evocair MDI [AF]	<sup>a</sup> Fluticasone + Salmeterol Cipla 250/25 [LR]
						<sup>a</sup> Pavtide [TX]	<sup>a</sup> SalplusF Inhaler 250/25 [SZ]
			<sup>B</sup> 8.00	*100.29	31.60	<sup>a</sup> Seretide MDI 250/25 [GK]	

#### ■ FLUTICASONE PROPIONATE + SALMETEROL

##### Authority required (STREAMLINED)

**15714**

Asthma

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

##### Authority required (STREAMLINED)

**15548**

Chronic obstructive pulmonary disease (COPD)

##### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

#### fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14450M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*92.29	31.60	<sup>a</sup> Fluticasone Salmeterol Cipla 500/50 [LR]	<sup>a</sup> PAVTIDE ACCUHALER 500/50 [TX]
						<sup>a</sup> Salfumix Easyhaler 500/50 [OX]	<sup>a</sup> SalplusF DPI 500/50 [SZ]
			<sup>B</sup> 8.00	*100.29	31.60	<sup>a</sup> Seretide Accuhaler 500/50 [GK]	

#### ■ INDACATEROL + MOMETASONE

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

##### Authority required (STREAMLINED)

**11360**

Asthma

##### **Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules**

12269R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.97	31.60	Aectura Breezhaler [NV]

**indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules**

12279G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.61	31.60	Aectura Breezhaler [NV]

**indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules**

12289T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	43.78	31.60	Aectura Breezhaler [NV]

**■ INDACATEROL + MOMETASONE**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15653**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules**

14332H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*62.49	31.60	Aectura Breezhaler [NV]

**indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules**

14441C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*105.77	31.60	Aectura Breezhaler [NV]

**indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules**

14333J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*74.11	31.60	Aectura Breezhaler [NV]

*Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids*

**■ ACLIDINIUM + FORMOTEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****7798**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

10565C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	79.67	31.60	Brimica Genuair [FK]

**■ ACLIDINIUM + FORMOTEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15691**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

14410K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*147.51	31.60	Brimica Genuair [FK]

**■ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)****12603**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

14606R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	74.80	31.60	Trimbow [EU]

**■ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**12349**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

12468F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	74.80	31.60	Trimbow [EU]

**■ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

**12603**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

13200R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	79.93	31.60	Trimbow [EU]

**■ BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15543**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

14310E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*137.27	31.60	Trimbow [EU]

▪ **BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**12349**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

12672Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	78.97	31.60	Breztri Aerosphere [AP]

▪ **BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15543**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

14536C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*146.03	31.60	Breztri Aerosphere [AP]

**FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)****12349**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

11379X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	85.35	31.60	Trelegy Ellipta 100/62.5/25 [GK]

**FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au/](http://www.nationalasthma.org.au/)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)****12603**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

12917W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	89.06	31.60	Trelegy Ellipta 200/62.5/25 [GK]

**■ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**15543**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

14346C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*159.43	31.60	Trelegy Ellipta 100/62.5/25 [GK]

**■ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

**15601**

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

## fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14382Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*167.23	31.60	Trelegy Ellipta 200/62.5/25 [GK]

### ■ INDACATEROL + GLYCOPYRRONIUM

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### Authority required (STREAMLINED)

**7798**

Chronic obstructive pulmonary disease (COPD)

#### **Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LABA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LABA and a LABA.

## indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

10156M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	86.99	31.60	ultibro breezhaler 110/50 [NV]

### ■ INDACATEROL + GLYCOPYRRONIUM

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### Authority required (STREAMLINED)

**15691**

Chronic obstructive pulmonary disease (COPD)

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LABA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LABA and a LABA.

## indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

14504J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*162.87	31.60	ultibro breezhaler 110/50 [NV]

### ■ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LABA, LABA or ICS monotherapy.



**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

**12603**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules**

12295D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	89.05	31.60	Energair Breezhaler [NV]

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules**

12298G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	73.22	31.60	Energair Breezhaler [NV]

**■ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

**15601**

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules**

14399W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*167.19	31.60	Energair Breezhaler [NV]

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules**

14471P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*133.95	31.60	Energair Breezhaler [NV]

**■ TIOTROPIUM + OLODATEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**7798**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

10557P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	75.04	31.60	Spolto Respimat [BY]

▪ **TIOTROPIUM + OLODATEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**15691**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

14530R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*137.77	31.60	Spolto Respimat [BY]

▪ **UMECLIDINIUM + VILANTEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

**7798**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

10188F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	86.98	31.60	Anoro Ellipta 62.5/25 [GK]

**■ UMECLIDINIUM + VILANTEROL**

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15691**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

14358Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*162.85	31.60	Anoro Ellipta 62.5/25 [GK]

**OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS***Glucocorticoids***■ BECLOMETASONE****beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations**

8406K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	20.53	21.98	Qvar 50 [IL]

**beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations**

8407L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	28.32	29.77	Qvar 100 [IL]

**■ BECLOMETASONE****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations**

8409N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	31.43	31.60	Qvar 100 Autohaler [IL]

**beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations**

8408M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	25.24	26.69	Qvar 50 Autohaler [IL]

**■ BECLOMETASONE****Restricted benefit**

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**beclomethasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14514X	±2	5	..	*49.41	31.60	Qvar 100 Autohaler [IL]

**beclomethasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14378R	±2	5	..	*37.03	31.60	Qvar 50 Autohaler [IL]

**■ BECLOMETASONE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**beclomethasone dipropionate 50 microgram/actuation inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14540G	±2	5	..	*27.61	29.06	Qvar 50 [IL]

**beclomethasone dipropionate 100 microgram/actuation inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14541H	±2	5	..	*43.19	31.60	Qvar 100 [IL]

**■ BUDESONIDE****budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2072C	±1	5	..	35.53	31.60	Pulmicort Turbuhaler [AP]

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2070Y	±1	5	..	22.76	24.21	Pulmicort Turbuhaler [AP]

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2071B	±1	5	..	30.14	31.59	Pulmicort Turbuhaler [AP]

**■ BUDESONIDE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14470N	±2	5	..	*57.61	31.60	Pulmicort Turbuhaler [AP]

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14331G	±2	5	..	*32.07	31.60	Pulmicort Turbuhaler [AP]

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14503H	±2	5	..	*46.83	31.60	Pulmicort Turbuhaler [AP]

**■ BUDESONIDE**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****6340**

Severe chronic asthma

**Clinical criteria:**

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2066R	±1	5	..	88.72	31.60	Pulmicort Respules [AP]

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2065Q	±1	5	..	88.72	31.60	Pulmicort Respules [AP]

■ **BUDESONIDE**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)****15578**

Severe chronic asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

14469M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*166.51	31.60	Pulmicort Respules [AP]

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

14438X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*166.51	31.60	Pulmicort Respules [AP]

■ **CICLESONIDE****ciclesonide 160 microgram/actuation inhalation, 120 actuations**

8854B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	33.24	31.60	Alvesco 160 [EU]

**ciclesonide 80 microgram/actuation inhalation, 120 actuations**

8853Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	24.30	25.75	Alvesco 80 [EU]

■ **CICLESONIDE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ciclesonide 160 microgram/actuation inhalation, 120 actuations**

14348E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*53.03	31.60	Alvesco 160 [EU]

**ciclesonide 80 microgram/actuation inhalation, 120 actuations**

14312G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*35.15	31.60	Alvesco 80 [EU]

■ **FLUTICASONE FUROATE****fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations**

11719T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	29.45	30.90	Arnuity Ellipta [GK]

**fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations**

11729H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	42.88	31.60	Arnuity Ellipta [GK]

■ **FLUTICASONE FUROATE****Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations**

14515Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*45.45	31.60	Arnuity Ellipta [GK]

**fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations**

14380W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*72.31	31.60	Arnuity Ellipta [GK]

## ■ FLUTICASONE PROPIONATE

## fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

8345F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	26.78	28.23	<sup>a</sup> Axotide [TX]	<sup>a</sup> Fluticasone Cipla Inhaler [LR]
			<sup>B</sup> 3.00	29.78	28.23	<sup>a</sup> Flixotide [GK]	

## fluticasone propionate 250 microgram/actuation inhalation, 120 actuations

8346G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	37.97	31.60	<sup>a</sup> Axotide [TX]	<sup>a</sup> Fluticasone Cipla Inhaler [LR]
			<sup>B</sup> 3.00	40.97	31.60	<sup>a</sup> Flixotide [GK]	

## fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

8147T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	19.32	20.77	<sup>a</sup> Axotide Junior Accuhaler [TX]	
			<sup>B</sup> 4.00	23.32	20.77	<sup>a</sup> Flixotide Junior Accuhaler [GK]	

## fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

8148W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	26.78	28.23	<sup>a</sup> Axotide Accuhaler [TX]	
			<sup>B</sup> 4.00	30.78	28.23	<sup>a</sup> Flixotide Accuhaler [GK]	

## fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations

8149X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	37.97	31.60	Flixotide Accuhaler [GK]	

## ■ FLUTICASONE PROPIONATE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

14347D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*40.11	31.60	<sup>a</sup> Axotide [TX]	<sup>a</sup> Fluticasone Cipla Inhaler [LR]
			<sup>B</sup> 6.00	*46.11	31.60	<sup>a</sup> Flixotide [GK]	

## fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

14412M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*25.19	26.64	<sup>a</sup> Axotide Junior Accuhaler [TX]	
			<sup>B</sup> 8.00	*33.19	26.64	<sup>a</sup> Flixotide Junior Accuhaler [GK]	

## fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

14381X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*40.11	31.60	<sup>a</sup> Axotide Accuhaler [TX]	
			<sup>B</sup> 8.00	*48.11	31.60	<sup>a</sup> Flixotide Accuhaler [GK]	

## ■ FLUTICASONE PROPIONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

**14180**

Asthma

**Clinical criteria:**

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.

## fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

8516F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	20.87	22.32	<sup>a</sup> Axotide Junior [TX]	
			<sup>B</sup> 4.00	24.87	22.32	<sup>a</sup> Flixotide Junior [GK]	

## ■ FLUTICASONE PROPIONATE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

**15854**

Asthma

**Clinical criteria:**

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years, **AND**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluticasone propionate 50 microgram/actuation inhalation, 120 actuations**

14487L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*28.29	29.74	<sup>a</sup> Axotide Junior [TX]
			<sup>B</sup> 8.00	*36.29	29.74	<sup>a</sup> Flixotide Junior [GK]

**Anticholinergics****■ ACLIDINIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations**

10124W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	59.37	31.60	Bretaris Genuair [FK]

**■ ACLIDINIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations**

14539F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*105.29	31.60	Bretaris Genuair [FK]

**■ GLYCOPYRRONIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

10059K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.37	31.60	seebri breezhaler [NV]

**■ GLYCOPYRRONIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

14417T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*105.29	31.60	seebri breezhaler [NV]

**■ IPRATROPIUM****ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations**

8671J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*34.61	31.60	Atrovent [BY]

**■ IPRATROPIUM****Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules**

1542E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*27.25	28.70	<sup>a</sup> Ipratrin [AF]
			<sup>B</sup> 0.44	*27.69	28.70	<sup>a</sup> Atrovent [BY]

**ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules**

8238N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.77	31.22	<sup>a</sup> Ipratrin Adult [AF]
			<sup>B</sup> 0.44	*30.21	31.22	<sup>a</sup> Atrovent Adult [BY]

**■ TIOTROPIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Restricted benefit**

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique,

**AND**

- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be at least 18 years of age.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

11043F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	44.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM**

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Restricted benefit**

Severe asthma

**Clinical criteria:**



- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be at least 18 years of age.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

14323W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****8606**

Severe asthma

**Treatment criteria:**

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.
- Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

11629C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	44.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)****15754**

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

14531T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

10509D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	44.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

14499D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

**■ TIOTROPIUM**

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### **Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

#### **tiotropium 13 microgram powder for inhalation, 30 capsules**

11892X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	39.57	31.60	<sup>a</sup> Braltus [TB]

#### **tiotropium 18 microgram powder for inhalation, 30 capsules**

14576E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	39.57	31.60	<sup>a</sup> Tiotropium Lupin [GQ]

#### **tiotropium 18 microgram powder for inhalation, 30 capsules**

8626B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	44.45	31.60	<sup>a</sup> Spiriva [BY]

### ■ TIOTROPIUM

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### **Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### **tiotropium 13 microgram powder for inhalation, 30 capsules**

14555C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*65.69	31.60	<sup>a</sup> Braltus [TB]

#### **tiotropium 18 microgram powder for inhalation, 30 capsules**

14361W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*75.45	31.60	<sup>a</sup> Spiriva [BY]

#### **tiotropium 18 microgram powder for inhalation, 30 capsules**

14574C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*65.69	31.60	<sup>a</sup> Tiotropium Lupin [GQ]

### ■ UMECLIDINIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

#### **Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

#### **umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations**

10187E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	59.37	31.60	Incruse Ellipta [GK]

### ■ UMECLIDINIUM

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations**

14389H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*105.29	31.60	Incruse Ellipta [GK]

**ADRENERGICS FOR SYSTEMIC USE***Alpha- and beta-adrenoreceptor agonists***■ ADRENALINE (EPINEPHRINE)**

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.10	22.55	Link Medical Products Pty Ltd [LM]

**■ ADRENALINE (EPINEPHRINE)**

**Caution** Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at [www.allergy.org.au](http://www.allergy.org.au).)

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
  - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
- The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device**

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*160.17	31.60	<sup>a</sup> Adrenaline Jr Viatris [AF] <sup>a</sup> EpiPen Jr. [AL]	<sup>a</sup> Anapen Junior 150 [XT]

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*160.17	31.60	<sup>a</sup> Adrenaline Viatris [AF] <sup>a</sup> EpiPen [AL]	<sup>a</sup> Anapen 300 [XT]

**adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device**

12655C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*160.17	31.60	Anapen 500 [XT]

*Selective beta-2-adrenoreceptor agonists***■ SALBUTAMOL****salbutamol 2 mg/5 mL oral liquid, 150 mL**

1103C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.19	28.64	Ventolin [GK]

**■ TERBUTALINE****terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

1034K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	26.74	28.19	Bricanyl [AP]

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES***Xanthines***■ THEOPHYLLINE**

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**theophylline 200 mg modified release tablet, 100**

8230E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.02	19.47	Nuelin-SR 200 [IL]

**theophylline 250 mg modified release tablet, 100**

2634P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.85	20.30	Nuelin-SR 250 [IL]

**theophylline 300 mg modified release tablet, 100**

8231F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.91	21.36	Nuelin-SR 300 [IL]

**theophylline 133.3 mg/25 mL oral liquid, 500 mL**

2614N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	18.32	19.77	Nuelin [IL]

*Leukotriene receptor antagonists***■ MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****6666**

Asthma

Treatment Phase: First-line prevention

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**montelukast 4 mg chewable tablet, 28**

8627C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.86	19.31	<sup>a</sup> APX-MONTELUKAST [TX] <sup>a</sup> Montelukast APOTEX [GX] <sup>a</sup> Montelukast Mylan [AF] <sup>a</sup> Montelukast Viatris [AL]	<sup>a</sup> MONTELAIR 4 [RF] <sup>a</sup> Montelukast Lupin [HQ] <sup>a</sup> Montelukast Sandoz 4 [SZ] <sup>a</sup> MONTELUKAST-WGR [WG]

**■ MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****6674**

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Authority required (STREAMLINED)****7781**

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**montelukast 5 mg chewable tablet, 28**

8628D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	17.76	19.21	<sup>a</sup> APX-MONTELUKAST [TX] <sup>a</sup> Montelukast APOTEX [GX] <sup>a</sup> Montelukast Mylan [AF] <sup>a</sup> Montelukast Viatris [AL]	<sup>a</sup> MONTELAIR 5 [RF] <sup>a</sup> Montelukast Lupin [HQ] <sup>a</sup> Montelukast Sandoz 5 [SZ] <sup>a</sup> MONTELUKAST-WGR [WG]

**■ MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)****15642**

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR

- The treatment must be an alternative to nedocromil sodium.

### montelukast 4 mg chewable tablet, 28

14526M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.27	23.72	<sup>a</sup> APX-MONTELUKAST [TX] <sup>a</sup> Montelukast APOTEX [GX] <sup>a</sup> Montelukast Mylan [AF] <sup>a</sup> Montelukast Viatris [AL]	<sup>a</sup> MONTELAIR 4 [RF] <sup>a</sup> Montelukast Lupin [HQ] <sup>a</sup> Montelukast Sandoz 4 [SZ] <sup>a</sup> MONTELUKAST-WGR [WG]

## ■ MONTELUKAST

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

**15643**

Asthma

Treatment Phase: First-line prevention

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

#### **Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

#### Authority required (STREAMLINED)

**15644**

Asthma

Treatment Phase: Prevention of condition

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

#### **Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

### montelukast 5 mg chewable tablet, 28

14553Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*22.07	23.52	<sup>a</sup> APX-MONTELUKAST [TX] <sup>a</sup> Montelukast APOTEX [GX] <sup>a</sup> Montelukast Mylan [AF] <sup>a</sup> Montelukast Viatris [AL]	<sup>a</sup> MONTELAIR 5 [RF] <sup>a</sup> Montelukast Lupin [HQ] <sup>a</sup> Montelukast Sandoz 5 [SZ] <sup>a</sup> MONTELUKAST-WGR [WG]

## ■ ANTIHISTAMINES FOR SYSTEMIC USE

### ANTIHISTAMINES FOR SYSTEMIC USE

*Phenothiazine derivatives*

## ■ PROMETHAZINE

### promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

1948M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	2	..	..	*36.65	31.60	DBL Promethazine Hydrochloride [PF]

## ■ SENSORY ORGANS

## ■ OPHTHALMOLOGICALS

### ANTIINFECTIVES

*Antibiotics*

## SENSORY ORGANS

### ■ AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Restricted benefit

Trachoma

#### azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	#29.06	30.93	Zithromax [PF]

#### azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	2	..	17.85	19.30	<sup>a</sup> APO-Azithromycin [TX] <sup>a</sup> Azithromycin Viatris [AL] <sup>a</sup> ZITHRO [RW]	<sup>a</sup> Azithromycin Sandoz [SZ] <sup>a</sup> AZITHROMYCIN-WGR [WG] <sup>a</sup> Zithromax [PF]

### ■ CHLORAMPHENICOL

#### Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

#### chloramphenicol 0.5% eye drops, 10 mL

11112W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP NP MW</b>	±1	2	..	17.57	19.02	Chlorsig [AS]

### ■ TOBRAMYCIN

#### Restricted benefit

Perioperative use in ophthalmic surgery

#### Restricted benefit

Suspected Pseudomonal eye infection

#### tobramycin 0.3% eye drops, 5 mL

5569D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	2	..	24.08	25.53	Tobrex [NV]

#### tobramycin 0.3% eye ointment, 3.5 g

5570E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	..	..	26.64	28.09	Tobrex [NV]

### ■ TOBRAMYCIN

#### Restricted benefit

Invasive ocular infection

#### Restricted benefit

Perioperative use in ophthalmic surgery

#### Restricted benefit

Suspected Pseudomonal eye infection

#### tobramycin 0.3% eye drops, 5 mL

2328M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	24.08	25.53	Tobrex [NV]

#### tobramycin 0.3% eye ointment, 3.5 g

2329N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	26.64	28.09	Tobrex [NV]

## Antivirals

### ■ ACICLOVIR

#### Restricted benefit

Herpes simplex keratitis

#### aciclovir 3% eye ointment, 4.5 g

1002R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	..	..	28.60	30.05	<sup>a</sup> ViruPOS [AE]	<sup>a</sup> XOROX [IX]

### ■ ACICLOVIR

#### Restricted benefit

Herpes simplex keratitis



**aciclovir 3% eye ointment, 4.5 g**

5501M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	..	..	28.60	30.05	<sup>a</sup> ViruPOS [AE]	<sup>a</sup> XOROX [IX]

**Fluoroquinolones**
**■ CIPROFLOXACIN**
**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

1217C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*43.69	31.60	<sup>a</sup> CiloQuin [NM]
			<sup>B</sup> 9.50	*53.19	31.60	<sup>a</sup> Ciloxan [NV]

**■ CIPROFLOXACIN**
**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

5564W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	..	..	*43.69	31.60	<sup>a</sup> CiloQuin [NM]
			<sup>B</sup> 9.50	*53.19	31.60	<sup>a</sup> Ciloxan [NV]

**■ OFLOXACIN**
**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

5567B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	..	..	*29.33	30.78	Ocuflox [VE]

**■ OFLOXACIN**
**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

8383F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.33	30.78	Ocuflox [VE]

**ANTIINFLAMMATORY AGENTS**
**Corticosteroids, plain**
**■ DEXAMETHASONE**
**dexamethasone 0.1% eye drops, 5 mL**

1288T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	23.59	25.04	Maxidex [NV]

**■ DEXAMETHASONE**
**Authority required**

Non-infectious posterior segment uveitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

## dexamethasone 700 microgram implant, 1

11317P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1211.74	31.60	Ozurdex [VE]

### ■ DEXAMETHASONE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

## dexamethasone 0.1% eye drops, 5 mL

5565X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	23.59	25.04	Maxidex [NV]

### ■ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

## dexamethasone 700 microgram implant, 1

10943Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1211.74	31.60	Ozurdex [VE]

### ■ DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13428**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**dexamethasone 700 microgram implant, 1**

13168C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1211.74	31.60	Ozurdex [VE]

▪ **DEXAMETHASONE**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

## **Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

## **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

## **Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

## **dexamethasone 700 microgram implant, 1**

11469P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1211.74	31.60	Ozurdex [VE]

## ▪ **DEXAMETHASONE**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required (STREAMLINED)**

**13387**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

## **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

## **Authority required (STREAMLINED)**

**13336**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

## **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

## **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

## **dexamethasone 700 microgram implant, 1**

13142Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1211.74	31.60	Ozurdex [VE]

## ▪ **HYDROCORTISONE ACETATE**

## **hydrocortisone acetate 1% eye ointment, 5 g**

2441L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.94	20.39	Hycor [AS]

## ■ HYDROCORTISONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

### hydrocortisone acetate 1% eye ointment, 5 g

5516H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	18.94	20.39	Hycor [AS]

*Corticosteroids and mydriatics in combination*

## ■ PREDNISOLONE ACETATE + PHENYLEPHRINE

### Restricted benefit

Severe eye inflammation

### Clinical criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

### Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

### prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

11908R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	24.12	25.57	Prednefrin Forte [VE]

## ■ PREDNISOLONE ACETATE + PHENYLEPHRINE

### Restricted benefit

Corneal grafts

### Restricted benefit

Uveitis

### prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

3112T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	24.12	25.57	Prednefrin Forte [VE]

## ■ PREDNISOLONE ACETATE + PHENYLEPHRINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

Uveitis

### prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

5568C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	24.12	25.57	Prednefrin Forte [VE]

## ANTIGLAUCOMA PREPARATIONS AND MIOTICS

*Sympathomimetics in glaucoma therapy*

## ■ BRIMONIDINE

### brimonidine tartrate 0.15% eye drops, 5 mL

5298W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	21.16	22.61	Alphagan P 1.5 [VE]

### brimonidine tartrate 0.2% eye drops, 5 mL

8351M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	21.63	23.08	<sup>a</sup> Enidin [VB]
			<sup>b</sup> 0.98	22.61	23.08	<sup>a</sup> Alphagan [VE]

## ■ BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### brimonidine tartrate 0.15% eye drops, 5 mL

5563T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	21.16	22.61	Alphagan P 1.5 [VE]

### brimonidine tartrate 0.2% eye drops, 5 mL

5534G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	21.63	23.08	<sup>a</sup> Enidin [VB]
			<sup>b</sup> 0.98	22.61	23.08	<sup>a</sup> Alphagan [VE]

## ■ BRIMONIDINE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### brimonidine tartrate 0.15% eye drops, 5 mL

14496Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*28.87	30.32	Alphagan P 1.5 [VE]

### brimonidine tartrate 0.2% eye drops, 5 mL

14497B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*29.81	31.26	<sup>a</sup> Enidin [VB]
			<sup>B</sup> 1.96	*31.77	31.26	<sup>a</sup> Alphagan [VE]

## ■ BRIMONIDINE + TIMOLOL

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

8826M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	26.18	27.63	Combigan [VE]

## ■ BRIMONIDINE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

5535H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	26.18	27.63	Combigan [VE]

## ■ BRIMONIDINE + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

14491Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*38.91	31.60	Combigan [VE]

## Parasympathomimetics

## ■ PILOCARPINE

### pilocarpine hydrochloride 1% eye drops, 15 mL

2595N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	18.77	20.22	Isopto Carpine [NV]

### pilocarpine hydrochloride 2% eye drops, 15 mL

2596P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	19.86	21.31	Isopto Carpine [NV]

**pilocarpine hydrochloride 4% eye drops, 15 mL**

2598R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	22.34	23.79	Isopto Carpine [NV]

**PILOCARPINE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**pilocarpine hydrochloride 1% eye drops, 15 mL**

5536J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	18.77	20.22	Isopto Carpine [NV]

**pilocarpine hydrochloride 2% eye drops, 15 mL**

5537K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	19.86	21.31	Isopto Carpine [NV]

**pilocarpine hydrochloride 4% eye drops, 15 mL**

5538L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	22.34	23.79	Isopto Carpine [NV]

**PILOCARPINE**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pilocarpine hydrochloride 1% eye drops, 15 mL**

14355M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*24.09	25.54	Isopto Carpine [NV]

**pilocarpine hydrochloride 2% eye drops, 15 mL**

14523J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*26.27	27.72	Isopto Carpine [NV]

**pilocarpine hydrochloride 4% eye drops, 15 mL**

14550T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*31.23	31.60	Isopto Carpine [NV]

**Carbonic anhydrase inhibitors**
**ACETAZOLAMIDE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**acetazolamide 250 mg tablet, 100**

1004W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	23.98	25.43	Diamox [RW]

**BRINZOLAMIDE**
**brinzolamide 1% eye drops, 5 mL**

8483L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	23.20	24.65	<sup>a</sup> BrinzoQuin [NM]
			<sup>B</sup> 4.80	28.00	24.65	<sup>a</sup> Azopt [NV]

**BRINZOLAMIDE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% eye drops, 5 mL**

5540N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	23.20	24.65	<sup>a</sup> BrinzoQuin [NM]
			<sup>B</sup> 4.80	28.00	24.65	<sup>a</sup> Azopt [NV]

**BRINZOLAMIDE**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## brinzolamide 1% eye drops, 5 mL

14321R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*32.95	31.60	<sup>a</sup> BrinzoQuin [NM]
			<sup>B</sup> 9.60	*42.55	31.60	<sup>a</sup> Azopt [NV]

## ■ BRINZOLAMIDE + BRIMONIDINE

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

## brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

10536M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	24.80	26.25	Simbrinza 1%/0.2% [NV]

## ■ BRINZOLAMIDE + BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

## brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

10547D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	24.80	26.25	Simbrinza 1%/0.2% [NV]

## ■ BRINZOLAMIDE + BRIMONIDINE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

## brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

14423D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*36.15	31.60	Simbrinza 1%/0.2% [NV]

## ■ BRINZOLAMIDE + TIMOLOL

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

## brinzolamide 1% + timolol 0.5% eye drops, 5 mL

3438Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	26.67	28.12	Azarga [NV]

## ■ BRINZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.



**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

5562R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	26.67	28.12	Azarga [NV]

**■ BRINZOLAMIDE + TIMOLOL**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

14495X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡2	5	..	*39.89	31.60	Azarga [NV]

**■ DORZOLAMIDE**
**dorzolamide 2% eye drops, 5 mL**

8488R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	18.76	20.21	<sup>a</sup> Trusamide [AF]	<sup>a</sup> Trusopt [MF]

**■ DORZOLAMIDE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

5541P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	18.76	20.21	<sup>a</sup> Trusamide [AF]	<sup>a</sup> Trusopt [MF]

**■ DORZOLAMIDE**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**dorzolamide 2% eye drops, 5 mL**

14524K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡2	5	..	*24.07	25.52	<sup>a</sup> Trusamide [AF]	<sup>a</sup> Trusopt [MF]

**■ DORZOLAMIDE + TIMOLOL**
**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

8567X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	21.99	23.44	<sup>a</sup> Cosdor [AF]	<sup>a</sup> Vizo-PF Dorzololam [AE]
			<sup>b</sup> 0.80	22.79	23.44	<sup>a</sup> Cosopt [MF]	

**■ DORZOLAMIDE + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

5542Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	21.99	23.44	<sup>a</sup> Cosdor [AF]	<sup>a</sup> Vizo-PF Dorzololam [AE]
			<sup>b</sup> 0.80	22.79	23.44	<sup>a</sup> Cosopt [MF]	

## ■ DORZOLAMIDE + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### **dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

14386E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±2	5	..	*30.53	31.60	<sup>a</sup> Cosdor [AF]	<sup>a</sup> Vizo-PF Dorzolotim [AE]
			<sup>B</sup> 1.60	*32.13	31.60	<sup>a</sup> Cosopt [MF]	

### *Beta blocking agents*

## ■ BETAXOLOL

### **betaxolol 0.5% eye drops, 5 mL**

2825Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	20.72	22.17	Betoptic [NV]

## ■ BETAXOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### **betaxolol 0.5% eye drops, 5 mL**

5544T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	20.72	22.17	Betoptic [NV]

## ■ BETAXOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### **betaxolol 0.5% eye drops, 5 mL**

14425F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*27.99	29.44	Betoptic [NV]

## ■ TIMOLOL

**Note** Pharmaceutical benefits that have the brand Timolol (Brown & Burk, UK) may be substituted for pharmaceutical benefits that have the brand Timoptol in the case of a shortage.

### **timolol 0.5% eye drops, 5 mL**

1279H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	21.73	23.18	<sup>a</sup> Timoptol [MF]

### **timolol 0.5% eye drops, 5 mL**

14657K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	42.71	31.60	<sup>a</sup> Timolol (Brown & Burk, UK) [LM]

## ■ TIMOLOL

**Note** Pharmaceutical benefits that have the brand Timoptol-LA 0.5 % (Santen Oy, Finland) may be substituted for pharmaceutical benefits that have the brand Timoptol XE in the case of shortage.

### **timolol 0.5% eye drops, 2.5 mL**

14611B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	44.75	31.60	<sup>a</sup> Timoptol-LA 0.5 % (Santen Oy, Finland) [LM]

### **timolol 0.5% eye drops, 2.5 mL**

1926J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	23.57	25.02	<sup>a</sup> Timoptol XE [MF]

## ■ TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Note** Pharmaceutical benefits that have the brand Timoptol-LA 0.5 % (Santen Oy, Finland) may be substituted for pharmaceutical benefits that have the brand Timoptol XE in the case of a shortage.

### timolol 0.5% eye drops, 2.5 mL

14634F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	44.75	31.60	<sup>a</sup> Timoptol-LA 0.5 % (Santen Oy, Finland) [LM]

### timolol 0.5% eye drops, 2.5 mL

5550D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	23.57	25.02	<sup>a</sup> Timoptol XE [MF]

## ■ TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Note** Pharmaceutical benefits that have the brand Timolol (Brown & Burk, UK) may be substituted for pharmaceutical benefits that have the brand Timoptol in the case of a shortage.

### timolol 0.5% eye drops, 5 mL

14649B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	42.71	31.60	<sup>a</sup> Timolol (Brown & Burk, UK) [LM]

### timolol 0.5% eye drops, 5 mL

5548B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	21.73	23.18	<sup>a</sup> Timoptol [MF]

## Prostaglandin analogues

## ■ BIMATOPROST

### bimatoprost 0.03% eye drops, 3 mL

8620Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	33.19	31.60	<sup>a</sup> Bimatoprost Sandoz [SZ] <sup>a</sup> Bimprozt [TY] <sup>a</sup> Lumigan [VE]	<sup>a</sup> BIMATOPROST-WGR [WG] <sup>a</sup> Bimtop [AF]

### bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

10046R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	30.03	31.48	Lumigan PF [VE]

## ■ BIMATOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### bimatoprost 0.03% eye drops, 3 mL

5551E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	33.19	31.60	<sup>a</sup> Bimatoprost Sandoz [SZ] <sup>a</sup> Bimprozt [TY] <sup>a</sup> Lumigan [VE]	<sup>a</sup> BIMATOPROST-WGR [WG] <sup>a</sup> Bimtop [AF]

### bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

10053D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	30.03	31.48	Lumigan PF [VE]

## ■ BIMATOPROST

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### bimatoprost 0.03% eye drops, 3 mL

14315K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±2	5	..	*52.93	31.60	<sup>a</sup> Bimatoprost Sandoz [SZ] <sup>a</sup> Bimprozt [TY] <sup>a</sup> Lumigan [VE]	<sup>a</sup> BIMATOPROST-WGR [WG] <sup>a</sup> Bimtop [AF]

### bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

14422C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*46.61	31.60	Lumigan PF [VE]

## ■ BIMATOPROST + TIMOLOL

### Restricted benefit

Elevated intra-ocular pressure

## Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

10107Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	34.78	31.60	GANfort PF 0.3/5 [VE]

## ▪ BIMATOPROST + TIMOLOL

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

9464D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	37.05	31.60	Ganfort 0.3/5 [VE]

## ▪ BIMATOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

5558M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	37.05	31.60	Ganfort 0.3/5 [VE]

### bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

10108B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	34.78	31.60	GANfort PF 0.3/5 [VE]

## ▪ BIMATOPROST + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

### Restricted benefit

Elevated intra-ocular pressure

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

14317M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*60.65	31.60	Ganfort 0.3/5 [VE]

### bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

14351H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*56.11	31.60	GANfort PF 0.3/5 [VE]

## ▪ LATANOPROST

### latanoprost 0.005% eye drops, 2.5 mL

8243W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	17.76	19.21	<sup>a</sup> APO-Latanoprost [TX]	<sup>a</sup> Latanoprost Sandoz [SZ]
						<sup>a</sup> LATANOPROST-WGR [WG]	<sup>a</sup> Xalaprost [AF]
						<sup>a</sup> Xalatan [AS]	

## ▪ LATANOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**latanoprost 0.005% eye drops, 2.5 mL**

5552F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	17.76	19.21	<sup>a</sup> APO-Latanoprost [TX] <sup>a</sup> LATANOPROST-WGR [WG] <sup>a</sup> Xalatan [AS]	<sup>a</sup> Latanoprost Sandoz [SZ] <sup>a</sup> Xalaprost [AF]

**■ LATANOPROST**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**latanoprost 0.005% eye drops, 2.5 mL**

14453Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±2	5	..	*22.07	23.52	<sup>a</sup> APO-Latanoprost [TX] <sup>a</sup> LATANOPROST-WGR [WG] <sup>a</sup> Xalatan [AS]	<sup>a</sup> Latanoprost Sandoz [SZ] <sup>a</sup> Xalaprost [AF]

**■ LATANOPROST + TIMOLOL**
**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

8895E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	21.61	23.06	<sup>a</sup> APO-Latanoprost/Timolol 0.05/5 [TX] <sup>a</sup> Xalamol 50/5 [AF]	<sup>a</sup> Xalacom [AS]

**■ LATANOPROST + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

5553G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	21.61	23.06	<sup>a</sup> APO-Latanoprost/Timolol 0.05/5 [TX] <sup>a</sup> Xalamol 50/5 [AF]	<sup>a</sup> Xalacom [AS]

**■ LATANOPROST + TIMOLOL**

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

14350G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±2	5	..	*29.77	31.22	<sup>a</sup> APO-Latanoprost/Timolol 0.05/5 [TX] <sup>a</sup> Xalamol 50/5 [AF]	<sup>a</sup> Xalacom [AS]

**■ TRAVOPROST**
**travoprost 0.004% eye drops, 2.5 mL**

8597L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	33.19	31.60	Travatan [NV]

## SENSORY ORGANS

### ■ TRAVOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### travoprost 0.004% eye drops, 2.5 mL

5554H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	33.19	31.60	Travatan [NV]

### ■ TRAVOPROST

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

#### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

#### travoprost 0.004% eye drops, 2.5 mL

14549R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*52.93	31.60	Travatan [NV]

### ■ TRAVOPROST + TIMOLOL

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

9057Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	36.14	31.60	Duotrav [NV]

### ■ TRAVOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

5555J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	36.14	31.60	Duotrav [NV]

### ■ TRAVOPROST + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

#### Restricted benefit

Elevated intra-ocular pressure

#### **Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

14316L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*58.83	31.60	Duotrav [NV]

## MYDRIATICS AND CYCLOPLEGICS

### Anticholinergics

### ■ ATROPINE SULFATE

#### atropine sulfate monohydrate 1% eye drops, 15 mL

1093M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	24.31	25.76	Atropt [AS]

## OCULAR VASCULAR DISORDER AGENTS

### Antineovascularisation agents

#### ■ AFLIBERCEPT

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

**13406**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

#### **aflibercept 8 mg/0.07 mL injection, 0.07 mL vial**

14594D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Eylea [BN]

#### ■ AFLIBERCEPT

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

**13402**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### **aflibercept 8 mg/0.07 mL injection, 0.07 mL vial**

14627W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	934.08	31.60	Eylea [BN]

#### ■ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health

Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

## **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

## **Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

## **aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

10505X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## **aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

12153P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## **■ AFLIBERCEPT**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

## **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

## **Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.



Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### **aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

12131L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

#### **aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

12141B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

### ■ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health

Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### **aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

2168D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

#### **aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

12152N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## ■ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required (STREAMLINED)

**13392**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

### **aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

13151E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

### **aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

13139M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## ■ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required (STREAMLINED)

**13406**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

### **aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

13146X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

### **aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

13167B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## ■ AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13402**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

13164W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	890.64	31.60	<sup>a</sup> Eylea [BN]

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

13150D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	890.64	31.60	<sup>a</sup> Eylea [BN]

■ **AFLIBERCEPT**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

11991D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

12132M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

■ **AFLIBERCEPT**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13387**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

**13336**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

13138L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

13141P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	890.64	31.60	<sup>a</sup> Eylea [BN]

## ■ AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

### **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication for the same eye prior to 1 October 2024, **AND**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only per eye. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the Continuing treatment criteria.

## aflibercept 8 mg/0.07 mL injection, 0.07 mL vial

14626T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Eylea [BN]

### ■ AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication for the same eye prior to 1 October 2024, **AND**
- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only per eye. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the Continuing treatment criteria.

#### **afibercept 8 mg/0.07 mL injection, 0.07 mL vial**

14635G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	934.08	31.60	Eylea [BN]

#### **▪ BROLUCIZUMAB**

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

##### **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

##### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

##### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

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##### **Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

##### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

##### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## brolocizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

12667Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	995.38	31.60	Beovu [NV]

### ■ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

## faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13177M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	934.08	31.60	Vabysmo [RO]

### ■ FARICIMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health



Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) A completed authority prescription form; and
- (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13183W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Vabysmo [RO]

▪ **FARICIMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13406**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13195L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Vabysmo [RO]

▪ **FARICIMAB**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13402**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

13198P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	934.08	31.60	Vabysmo [RO]

▪ **FARICIMAB**

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

14737P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Vabysmo [RO]

#### ■ FARICIMAB

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

##### **13387**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### Authority required (STREAMLINED)

##### **13336**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

14738Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	934.08	31.60	Vabysmo [RO]

#### ■ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) A completed authority prescription form; and
- (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

1382R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

10138N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

▪ **RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) A completed authority prescription form; and
- (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

#### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

10374B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

### ■ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

**13402**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

13165X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

#### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

13134G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

### ■ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

**13406**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13137K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13157L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

▪ **RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) A completed authority prescription form; and  
 (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  
 All reports must be documented in the patient's medical records.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

11471R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

11480F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

▪ **RANIBIZUMAB**

- Note** Special Pricing Arrangements apply.  
**Note** No increase in the maximum number of repeats may be authorised.  
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.  
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.  
**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.  
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema  
 Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) A completed authority prescription form; and  
 (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority required**

Central retinal vein occlusion with macular oedema  
 Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**

- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

#### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

11981N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

#### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

11975G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

### ■ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required (STREAMLINED)

##### **13392**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

#### Authority required (STREAMLINED)

##### **13340**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

#### **Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

#### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

13156K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

#### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

13143R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

### ■ RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.



- Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.
- Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**13387**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

**13336**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13149C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13166Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	786.36	31.60	<sup>a</sup> Lucentis [NV]

**OTHER OPHTHALMOLOGICALS**

*Other ophthalmologicals*

▪ **CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome

**carbomer-980 0.2% eye gel, 10 g**

5503P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	16.81	18.26	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [UL]
			<sup>B</sup> 3.85	20.66	18.26	<sup>a</sup> Viscotears [UO]	

**carbomer-980 0.2% eye gel, 10 g**

8384G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	16.81	18.26	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [UL]
			<sup>B</sup> 3.85	20.66	18.26	<sup>a</sup> Viscotears [UO]	

▪ **CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**carbomer-980 0.2% eye gel, 10 g**

14385D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>OP NP</b>	±2	5	..	*20.17	21.62	<sup>a</sup> Optifresh eye gel [PP]	<sup>a</sup> PAA [UL]
			<sup>B</sup> 7.70	*27.87	21.62	<sup>a</sup> Viscotears [UO]	

▪ **CARBOMER-980**

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

5504Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*31.14	31.60	Viscotears Gel PF [UO]

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

8578L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*31.14	31.60	Viscotears Gel PF [UO]

▪ **CARBOMER-980**

**Authority required (STREAMLINED)**

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

14420Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	6	5	..	*48.81	31.60	Viscotears Gel PF [UO]

▪ **CARMELLOSE SODIUM**

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 0.5% eye drops, 10 mL**

11852T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	25.01	26.46	Evolve Carmellose [CX]

**carmellose sodium 0.5% eye drops, 10 mL**

11853W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	25.01	26.46	Evolve Carmellose [CX]

▪ **CARMELLOSE SODIUM**

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 0.5% eye drops, 10 mL**

14319P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*36.57	31.60	Evolve Carmellose [CX]

▪ **CICLOSPORIN**

**Caution** It is recommended that the potential for immunosuppression with long term use of this drug be clinically reviewed after at least 24 months of treatment, if not already reviewed.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Chronic severe dry eye disease with keratitis

Treatment Phase: Initial treatment for up to the first 180 days of treatment

**Clinical criteria:**

- Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber, **AND**
- Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation, **AND**
- The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute, **AND**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines, **AND**
- Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.

**Population criteria:**

- Patient must be at least 18 years of age.

**Prescribing instruction:**

State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).

**Note** The Oxford scale, modified Oxford scale and Ocular Surface Disease Index (OSDI) were relied upon in the submission supporting initial PBS listing.

The Oxford scale uses a chart system consisting of a series of panels, labelled A to E in order of increasing severity. In each chart, staining is represented by dots. To grade staining, comparisons are made between the panels and the appearance of staining on the exposed interpalpebral conjunctiva and cornea of the patient. The details of the chart are presented in Figure 1 and, in a simplified form in Figure 4 (where the criteria, dot count and log columns are not displayed), in the following literature article: Bron A, Evans V, Smith, J. Grading of corneal and conjunctival staining in the context of other dry eye tests. *Cornea*. 2003;22(7):640-650.

The modified Oxford scale is as above, but with the first grade depiction (Grade 0), termed 'Grade 0.5'.

A list of equivalent scales to the Oxford scale is not provided. Prescribers should be satisfied that a scale other than the Oxford scale, if used, is equivalent to the Oxford scale.

The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function.

The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.

The OSDI questionnaire asks the following:

Presence of ocular symptoms - Have you experienced any of the following during the last week?

1. Eyes that are sensitive to light
2. Eyes that feel gritty
3. Painful or sore eyes
4. Blurred vision
5. Poor vision

Impact on daily activities - Have you had problems with your eyes limited you in performing any of the following during the last week?

1. Reading
2. Driving at night
3. Working with a computer or bank machine (ATM)
4. Watching TV

Environmental factors - Have your eyes felt uncomfortable in any of the following situations during the last week?

1. Windy conditions
2. Places or areas with low humidity (very dry)
3. Areas that are airconditioned

Rate responses on a scale of 0 to 4; 0 = none of the time, 1 = some of the time, 2 = half of the time, 3 = most of the time, and 4 = all of the time.

Further information on this index is in the following literature article: Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. *Drug Information Journal*. 1997;31:1436

The 'Dry Eye OSDI' Questionnaire' app developed by Allergan Inc is available to download for iPhone.

**Note** If the maximum number of repeats stated in this listing is not requested in this application, further supplies can be obtained through this treatment phase listing to continue treatment for up to the first 180 days of treatment, but the OSDI score and CFS grade need not be re-stated. Alternatively, treatment may be continued under the 'Continuing treatment' phase listing, provided the patient meets all eligibility criteria specified in that treatment phase listing.

**Authority required**

Chronic severe dry eye disease with keratitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application, **AND**
- The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; OR
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.

Prescribing instructions:

State in the first continuing treatment authority application for this drug:

(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application).

State in all continuing treatment authority applications:

(ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).

**ciclosporin 0.09% eye drops, 60 x 0.25 mL ampoules**

13284E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	1	5	..	83.35	31.60	Cequa [RA]

**ciclosporin 0.1% eye drops, 30 x 0.3 mL ampoules**

12663L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	83.35	31.60	Ikervis [CS]

▪ **DEXTRAN-70 + HYPROMELLOSE**

Restricted benefit

Severe dry eye syndrome

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

1509K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	17.22	18.67	<sup>a</sup> Poly-Tears [IQ]
			<sup>B</sup> 4.00	21.22	18.67	<sup>a</sup> Tears Naturale [AQ]

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

5520M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	17.22	18.67	<sup>a</sup> Poly-Tears [IQ]
			<sup>B</sup> 4.00	21.22	18.67	<sup>a</sup> Tears Naturale [AQ]

▪ **DEXTRAN-70 + HYPROMELLOSE**

Restricted benefit

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

14521G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*20.99	22.44	<sup>a</sup> Poly-Tears [IQ]
			<sup>B</sup> 8.00	*28.99	22.44	<sup>a</sup> Tears Naturale [AQ]

▪ **HYALURONATE SODIUM**

**Note** The in-use shelf life of this product is 6 months from the date of opening

Authority required (STREAMLINED)

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hyaluronate sodium 0.1% eye drops, 10 mL**

2181T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	34.81	31.60	Hylo-Fresh [AE]

**hyaluronate sodium 0.1% eye drops, 10 mL**

2184Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	34.81	31.60	Hylo-Fresh [AE]

**hyaluronate sodium 0.2% eye drops, 10 mL**

2171G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	34.81	31.60	Hylo-Forte [AE]

**hyaluronate sodium 0.2% eye drops, 10 mL**

2253N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	34.81	31.60	Hylo-Forte [AE]

▪ **HYALURONATE SODIUM**

**Note** The in-use shelf life of this product is 6 months from the date of opening

Authority required (STREAMLINED)

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**hyaluronate sodium 0.1% eye drops, 10 mL**

14354L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*56.17	31.60	Hylo-Fresh [AE]

**hyaluronate sodium 0.2% eye drops, 10 mL**

14494W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*56.17	31.60	Hylo-Forte [AE]

**■ HYPROMELLOSE**
**Restricted benefit**

Severe dry eye syndrome

**hypromellose 0.5% eye drops, 15 mL**

2956N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	17.22	18.67	Methopt [AF]

**hypromellose 0.5% eye drops, 15 mL**

5517J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	17.22	18.67	Methopt [AF]

**hypromellose 0.3% w/w eye drops, 10 mL**

11625W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.17	17.62	Revive Tears [PP]

**hypromellose 0.3% w/w eye drops, 10 mL**

11634H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	16.17	17.62	Revive Tears [PP]

**■ HYPROMELLOSE**
**Restricted benefit**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**hypromellose 0.5% eye drops, 15 mL**

14320Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*20.99	22.44	Methopt [AF]

**hypromellose 0.3% w/w eye drops, 10 mL**

14318N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*18.89	20.34	Revive Tears [PP]

**■ HYPROMELLOSE**
**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**
**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hypromellose 0.3% w/v eye drops, 10 mL**

11842G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	25.01	26.46	Evolve Hypromellose [CX]

**hypromellose 0.3% w/v eye drops, 10 mL**

11849P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	25.01	26.46	Evolve Hypromellose [CX]

**■ HYPROMELLOSE**
**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**hypromellose 0.3% w/v eye drops, 10 mL**

14492R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP NP</b>	±2	5	..	*36.57	31.60	Evolve Hypromellose [CX]

▪ **LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE**

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL**

12612T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP NP</b>	±1	5	..	35.80	31.60	Cationorm [CS]

▪ **LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE**

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL**

14352J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP NP</b>	±2	5	..	*58.15	31.60	Cationorm [CS]

▪ **PARAFFIN**

**paraffin 1 g/g eye ointment, 3.5 g**

1754H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*21.17	22.62	Poly Visc [IQ]

**paraffin 1 g/g eye ointment, 3.5 g**

5523Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	2	5	..	*21.17	22.62	Poly Visc [IQ]

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

1750D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	20.84	22.29	Poly Visc [IQ]

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

5522P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	±1	5	..	20.84	22.29	Poly Visc [IQ]

▪ **PARAFFIN**

**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**paraffin 1 g/g eye ointment, 3.5 g**

14353K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP NP</b>	4	5	..	*28.87	30.32	Poly Visc [IQ]

**paraffin 1 g/g eye ointment, 2 x 3.5 g**

14493T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*28.23	29.68	Poly Visc [IQ]

**PERFLUOROHEXYLOCTANE**

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**perfluorohexyloctane 100% eye drops, 3 mL**

11439C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	1	5	..	33.89	31.60	Novatears [AE]

**perfluorohexyloctane 100% eye drops, 3 mL**

11446K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.89	31.60	Novatears [AE]

**PERFLUOROHEXYLOCTANE**

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**Authority required (STREAMLINED)**

**15559**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**perfluorohexyloctane 100% eye drops, 3 mL**

14424E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	2	5	..	*54.33	31.60	Novatears [AE]

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**
**Restricted benefit**

Severe dry eye syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

5524R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	15.98	17.43	<sup>a</sup> Optix [PP]	<sup>a</sup> Systane [AQ]

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

8676P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	15.98	17.43	<sup>a</sup> Optix [PP]	<sup>a</sup> Systane [AQ]

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**
**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

13100L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*34.41	31.60	Systane [AQ]

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

13113E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*34.41	31.60	Systane [AQ]

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**
**Restricted benefit**

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

## polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

14421B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP NP	±2	5	..	*18.51	19.96	<sup>a</sup> Optix [PP]	<sup>a</sup> Systane [AQ]

## ■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

### Authority required (STREAMLINED)

**15559**

Severe dry eye syndrome

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

## polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

14520F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	4	5	..	*55.35	31.60	Systane [AQ]

## ■ PROPYLENE GLYCOL

**Note** The in-use shelf life of this product is 6 months from the date of opening

### Restricted benefit

Severe dry eye syndrome

## propylene glycol 0.6% eye drops, 10 mL

14768G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±1	5	..	16.43	17.88	Systane Balance [AQ]

## ■ SOY LECITHIN + TOCOPHEROL + VITAMIN A

### Authority required (STREAMLINED)

**6172**

Severe dry eye syndrome

### Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

## soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

5545W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*29.75	31.20	tearsagain [RB]

## soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

9448G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*29.75	31.20	tearsagain [RB]

## ■ SOY LECITHIN + TOCOPHEROL + VITAMIN A

### Authority required (STREAMLINED)

**15559**

Severe dry eye syndrome

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

## soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

14426G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	4	5	..	*46.03	31.60	tearsagain [RB]

## ■ OTOLOGICALS

### ANTIINFECTIVES

#### Antiinfectives

## ■ CIPROFLOXACIN

### Authority required

Chronic suppurative otitis media

### Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

### Authority required

Chronic suppurative otitis media

### Population criteria:



- Patient must be less than 18 years of age.
- Clinical criteria:**
- Patient must have perforation of the tympanic membrane.

**Authority required**

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have a grommet in situ.

**ciprofloxacin 0.3% ear drops, 5 mL**

2480M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	39.89	31.60	Ciloxan [NV]

**CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION***Corticosteroids and antiinfectives in combination***■ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE****framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

2781J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	17.22	18.67	<sup>a</sup> Otodex [FQ]
			<sup>B</sup> 2.25	19.47	18.67	<sup>a</sup> Sofradex [PB]

**■ TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN****triamcinolone acetonide 0.09% + neomycin 0.225% + gramicidin 0.0225% + nystatin 90 000 units/mL ear drops, 7.5 mL**

2971J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	17.65	19.10	<sup>a</sup> Otocomb Otic [LN]
			<sup>B</sup> 1.58	19.23	19.10	<sup>a</sup> Kenacomb Otic [AS]

**triamcinolone acetonide 0.1% + neomycin 0.25% + gramicidin 0.025% + nystatin 100 000 units/g ointment, 5 g**

2974M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	16.37	17.82	<sup>a</sup> Otocomb Otic [LN]
			<sup>B</sup> 2.66	19.03	17.82	<sup>a</sup> Kenacomb Otic [AS]

**■ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS****ANTIINFECTIVES***Antiinfectives***■ FRAMYCETIN SULFATE****framycetin sulfate 0.5% eye/ear drops, 8 mL**

1440T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	‡1	2	..	16.72	18.17	Soframycin [PB]

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

5557L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	16.72	18.17	Soframycin [PB]

**■ VARIOUS****■ ALLERGENS****ALLERGENS***Allergen extracts***■ HONEY BEE VENOM****honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10621B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	297.90	31.60	Hymenoptera Honey Bee Venom [DE]

**honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

2886X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	364.08	31.60	Albey Bee Venom [DE]

## ■ PAPER WASP VENOM

**Note** Paper wasp venom is not European wasp venom

### paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10620Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	348.16	31.60	Hymenoptera Paper Wasp Venom [DE]

### paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2918N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	364.08	31.60	Albey Paper Wasp Venom [DE]

## ■ YELLOW JACKET VENOM

### yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10622C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	402.89	31.60	Hymenoptera Yellow Jacket Venom [DE]

### yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2883R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	364.08	31.60	Albey Yellow Jacket Venom [DE]

## ■ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Antidotes*

## ■ NALOXONE

### naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

11816X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	±1	..	..	66.47	31.60	Nyxoid [MF]

### naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation

11817Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	±1	..	..	66.47	31.60	Nyxoid [MF]

### naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	30.90	31.60	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF]	<sup>a</sup> Naloxone Juno [JU]
						<sup>a</sup> NALOXONE SXP [XN]	

### naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>DP</b>	1	..	..	30.90	31.60	<sup>a</sup> Naloxone Hydrochloride (DBL) [PF]	<sup>a</sup> Naloxone Juno [JU]
						<sup>a</sup> NALOXONE SXP [XN]	

### naloxone hydrochloride 1 mg/mL injection, 2 mL syringe

11077B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>DP</b>	1	..	..	69.45	31.60	Prenoxad [FF]

### naloxone hydrochloride 1 mg/mL injection, 2 mL syringe

11078C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP MW</b>	1	..	..	69.45	31.60	Prenoxad [FF]

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

## ■ LANTHANUM

**Authority required (STREAMLINED)**

**5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

9403X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	195.19	31.60	Fosrenol [TK]

**lanthanum 750 mg chewable tablet, 6 x 15**

9404Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	290.43	31.60	Fosrenol [TK]

**lanthanum 1 g chewable tablet, 6 x 15**

9405B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	325.89	31.60	Fosrenol [TK]

**■ LANTHANUM****Authority required (STREAMLINED)****14872**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

14060B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*381.93	31.60	Fosrenol [TK]

**lanthanum 750 mg chewable tablet, 6 x 15**

13986D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*572.39	31.60	Fosrenol [TK]

**lanthanum 1 g chewable tablet, 6 x 15**

13874F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*643.31	31.60	Fosrenol [TK]

**■ PATIROMER****Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note Special Pricing Arrangements apply.****Authority required (STREAMLINED)****14327**

Chronic hyperkalaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor.

**Treatment criteria:**

- Patient must not be undergoing dialysis.

**patiromer 8.4 g powder for oral liquid, 30 sachets**

13609G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	376.38	31.60	Veltassa [CS]

**patiomer 16.8 g powder for oral liquid, 30 sachets**

13613L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	376.38	31.60	Veltassa [CS]

**■ PATIOMER**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hyperkalaemia

Treatment Phase: Initial PBS-subsidised treatment (including grandfathered patients)

**Population criteria:**

- Patient must have stage 3 to stage 4 chronic kidney disease.

**Clinical criteria:**

- The condition must be inadequately controlled by a low potassium diet., **AND**
- Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; OR
- Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.

**patiomer 8.4 g powder for oral liquid, 30 sachets**

13610H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	376.38	31.60	Veltassa [CS]

**patiomer 16.8 g powder for oral liquid, 30 sachets**

13620W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	376.38	31.60	Veltassa [CS]

**■ SEVELAMER**

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**

**5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer carbonate 800 mg tablet, 180**

11856B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	5	..	187.75	31.60	<sup>a</sup> ARX-SEVELAMER [XT] <sup>a</sup> Sevelamer Lupin [GQ]	<sup>a</sup> Sevelamer Apotex [TX]

**sevelamer hydrochloride 800 mg tablet, 180**

2142R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	187.75	31.60	<sup>a</sup> Renagel [GZ]

**■ SEVELAMER**

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**

**14872**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer carbonate 800 mg tablet, 180**

14027G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*367.03	31.60	<sup>a</sup> ARX-SEVELAMER [XT] <sup>a</sup> Sevelamer Lupin [GQ]	<sup>a</sup> Sevelamer Apotex [TX]

**sevelamer hydrochloride 800 mg tablet, 180**

13934J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*367.03	31.60	<sup>a</sup> Renagel [GZ]

**▪ SUCROFERRIC OXYHYDROXIDE****Authority required (STREAMLINED)****5491**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

10250L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	392.31	31.60	Velphoro [VL]

**▪ SUCROFERRIC OXYHYDROXIDE****Authority required (STREAMLINED)****14872**

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

13985C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*776.15	31.60	Velphoro [VL]

***Detoxifying agents for antineoplastic treatment*****▪ FOLINIC ACID****folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules**

1610R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	55.29	31.60	Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

**▪ FOLINIC ACID****Restricted benefit**

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

**folic acid 15 mg tablet, 10**

2308L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	95.18	31.60	Leucovorin Calcium (Hospira Pty Limited) [PF]

▪ **MESNA****Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

**mesna 1 g/10 mL injection, 15 x 10 mL ampoules**

8079F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	140.73	31.60	Uromitexan [BX]

**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

8078E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	69.09	31.60	Uromitexan [BX]

*Drugs for treatment of hypercalcaemia*▪ **PHOSPHORUS****Authority required (STREAMLINED)****5089**

Hypophosphataemic rickets

**Authority required (STREAMLINED)****5114**

Vitamin D-resistant rickets

**Authority required (STREAMLINED)****5095**

Familial hypophosphataemia

**Authority required (STREAMLINED)****5123**

Hypercalcaemia

**phosphorus 500 mg effervescent tablet, 100**

2946C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	81.83	31.60	PHOSPHATE PHEBRA [FG]

NP

▪ **PHOSPHORUS****Authority required (STREAMLINED)****14874**

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14962**

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14921**

Familial hypophosphataemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority required (STREAMLINED)****14922**

Hypercalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**phosphorus 500 mg effervescent tablet, 100**

13850Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*152.03	31.60	PHOSPHATE PHEBRA [FG]

*Other therapeutic products***■ POLYLACTIC ACID**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe facial lipoatrophy

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

9475Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*288.47	31.60	Sculptra [GA]

**■ POLYLACTIC ACID**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe facial lipoatrophy

Treatment Phase: Maintenance PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**polylactic acid 150 mg injection, 1 vial**

9476R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*288.47	31.60	Sculptra [GA]

**■ DIAGNOSTIC AGENTS****URINE TESTS****■ GLUCOSE AND KETONE INDICATOR URINE****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose and ketone indicator urine diagnostic strip, 50**

3107M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*21.25	22.70	Keto-Diastix [DX]

**■ GENERAL NUTRIENTS****OTHER NUTRIENTS****■ MEDIUM CHAIN TRIGLYCERIDES**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6181**

Chylous ascites

**Authority required (STREAMLINED)**

**6134**

Chylothorax

**Authority required (STREAMLINED)**

**6164**

Fat malabsorption

**Clinical criteria:**

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)****6203**

Hyperlipoproteinaemia type 1

**Authority required (STREAMLINED)****6155**

Intractable childhood epilepsy

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)****6135**

Cerebrospinal fluid glucose transporter defect

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority required (STREAMLINED)****6146**

Long chain fatty acid oxidation disorders

**medium chain triglycerides oral liquid, 250 mL bottle**

9327X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*170.59	31.60	Liquigen [SB]

**medium chain triglycerides oral oil, 500 mL**

3128P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*114.57	31.60	MCT Oil [SB]

**■ PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Population criteria:**

- Patient must be aged from 1 to 10 years inclusive.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 12 x 500 mL bottles**

11939J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	5	..	*1583.74	31.60	Nutrini Peptisorb Energy [NU]

*Fat/carbohydrates/proteins/minerals/vitamins, combinations*

**■ AMINO ACID SYNTHETIC FORMULA**

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and



(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula powder for oral liquid, 400 g**

1521C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*439.23	31.60	Neocate Junior Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

2250K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*439.23	31.60	EleCare [AB]

■ **AMINO ACID SYNTHETIC FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula powder for oral liquid, 400 g**

1180D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*295.63	31.60	Neocate Junior Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8574G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*295.63	31.60	EleCare [AB]

■ **AMINO ACID SYNTHETIC FORMULA**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula powder for oral liquid, 400 g**

1192R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*295.63	31.60	Neocate Junior Vanilla [SB]

**amino acid synthetic formula powder for oral liquid, 400 g**

8575H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*295.63	31.60	EleCare [AB]

## ■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2246F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*316.83	31.60	Neocate LCP [SB]

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9339M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*236.35	31.60	EleCare LCP [AB]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

### **amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

2560R

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*316.83	31.60	Neocate LCP [SB]

### **amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

9340N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*236.35	31.60	EleCare LCP [AB]

## **■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

1545H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	12	5	..	*471.03	31.60	Neocate Gold [SB]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5466Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*316.83	31.60	Neocate Gold [SB]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5467R

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*316.83	31.60	Neocate Gold [SB]

NP

## ■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

### **Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

### **Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Cows' milk anaphylaxis

### **Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

### **Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

### **Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

### **Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

Severe intestinal malabsorption including short bowel syndrome

### **Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

### **Authority required**



Eosinophilic oesophagitis  
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g**

13615N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*316.83	31.60	Alfamino [NT]

**■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g

13627F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*316.83	31.60	Alfamino [NT]

## ■ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6174**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

**6193**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

**6204**

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

**6137**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

**6182**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

**6194**

Biliary atresia

**Authority required (STREAMLINED)**

**6157**

Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

**6205**

Chylous ascites

**Authority required (STREAMLINED)**

**6195**

Cystic fibrosis

**Authority required (STREAMLINED)**

**6158**

Enterokinase deficiency

**Authority required (STREAMLINED)**

**6166**

Proven fat malabsorption

**Authority required (STREAMLINED)**

**6148**

Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**


- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

**6138**

Severe intestinal malabsorption including short bowel syndrome

**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

8259Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*202.67	31.60	Aptamil Gold+ Pepti-Junior [NU]

▪ **TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

10152H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*404.35	31.60	Monogen [SB]

**triglycerides medium chain formula powder for oral liquid, 400 g**

10155L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*365.31	31.60	Lipistart [VF]

▪ **TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula powder for oral liquid, 400 g**

10154K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*265.23	31.60	Peptamen Junior [NT]

▪ **TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula oral liquid, 12 x 500 mL bottles**

12948L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*1553.07	31.60	Nutrini Peptisorb [SB]

▪ **TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**

Hyperlipoproteinaemia type 1

**Restricted benefit**

Long chain fatty acid oxidation disorders

**Restricted benefit**

Chylous ascites

**Restricted benefit**

Chyllothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

1938B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*365.31	31.60	Lipistart [VF]

**triglycerides medium chain formula powder for oral liquid, 400 g**

8478F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*404.35	31.60	Monogen [SB]

**Carbohydrates****■ MODIFIED LONG CHAIN AMYLOPECTIN****Restricted benefit**

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

9386B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*652.31	31.60	Glycosade [VF]

**Amino acids/carbohydrates/minerals/vitamins, combinations****■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES****Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

10522T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*344.35	31.60	Alfamino Junior [NT]

### amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

11161K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*344.35	31.60	Neocate Junior [SB]

## ■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

### **amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

10527C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*344.35	31.60	Alfamino Junior [NT]

### **amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

11183N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*344.35	31.60	Neocate Junior [SB]

### **Milk substitutes**

#### **▪ MILK POWDER SYNTHETIC LOW CALCIUM**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Hypercalcaemia

**Population criteria:**

- Patient must be under the age of 4 years.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

3092R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*364.59	31.60	Locasol [SB]

*Other combinations of nutrients*
**■ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

11343B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	12	5	..	*477.51	31.60	Neocate Syneo [SB]

**■ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**



Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

11331J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*321.23	31.60	Neocate Syneo [SB]

**■ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Note** A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

11340W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*321.23	31.60	Neocate Syneo [SB]

▪ **AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE**

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate without phenylalanine modified release tablet, 6 x 77**

12072J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1323.11	31.60	PKU Easy Tablet [OH]

▪ **AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine powder for oral liquid, 30 x 20 g sachets**

10806R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*957.79	31.60	PKU Go [OH]

▪ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE**

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate without methionine modified release tablet, 6 x 77**

12006X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*2962.77	31.60	HCU Easy Tablet [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g**

10683G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	5	..	*1850.65	31.60	PKU Easy Microtabs [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE****Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate without phenylalanine and tyrosine modified release tablet, 6 x 77**

12015J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2402.75	31.60	TYR Easy Tablet [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE****Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition**Restricted benefit**

Maple syrup urine disease

**amino acid formula with fat, carbohydrate without valine, leucine and isoleucine modified release tablet, 6 x 77**

12014H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*2962.77	31.60	MSUD Easy Tablet [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine tablet: modified release, 6 x 100 g**

14782B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	5	..	*1737.11	31.60	PKU Easy Microtabs Plus [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles**

3417W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2181.79	31.60	HCU Anamix junior LQ [SB]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles**

10632N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1827.67	31.60	PKU Easy Shake & Go [OH]

**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID****Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles**

9330C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1632.11	31.60	TYR Anamix junior LQ [SB]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE**

**Restricted benefit**

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements, without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g bottles**

10934L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2826.83	31.60	TYR Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g**

12650T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*336.55	31.60	Essential Care Jr [QH]

## **■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### **amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 800 g**

12643K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*336.55	31.60	Essential Care Jr [QH]

### **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

### **amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets**

10715Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*1832.11	31.60	GA1 Anamix Junior [NU]

### **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

### **amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g**

2650L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*666.99	31.60	GA1 Anamix infant [SB]

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10466W	9	5	..	*2670.24	31.60	XLYS, LOW TRY Maxamum [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN****Restricted benefit**

Proven glutaric aciduria type 1

**Restricted benefit**

Pyridoxine dependent epilepsy

**Clinical criteria:**

- Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9438R	4	5	..	*1832.11	31.60	GA gel [VF]

**amino acid formula with vitamins and minerals without lysine and low in tryptophan containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14781Y	8	5	..	*1832.11	31.60	GA explore5 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 125 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1548L	3	5	..	*2560.35	31.60	HCU Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8744F	4	5	..	*2560.39	31.60	HCU express 15 [VF]

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2640Y	4	5	..	*3359.63	31.60	HCU cooler 20 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10693T	4	5	..	*1743.79	31.60	HCU Anamix Junior [NU]

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 29 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12273Y	4	5	..	*3359.63	31.60	HCU Lophlex [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE****Restricted benefit**

Pyridoxine non-responsive homocystinuria

**Population criteria:**

- Patient must be an infant or a very young child.

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8417B	8	5	..	*634.11	31.60	HCU Anamix infant [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE****Restricted benefit**

Methylmalonic acidemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g**

8058D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*634.11	31.60	MMA/PA Anamix infant [SB]

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets**

3443F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2560.39	31.60	MMA/PA express 15 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE****Restricted benefit**

Methylmalonic acidaemia

**Restricted benefit**

Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 18 g sachets**

10730R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1743.71	31.60	MMA/PA Anamix Junior [NU]

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

14775P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1743.71	31.60	MMA/PA explore5 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE****Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g tubs**

2806Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*1520.64	31.60	PKU Lophlex Sensation 20 [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets**

5483N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*868.55	31.60	PKU squeeze [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches**

14290D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1672.95	31.60	PKU Lophlex Select LQ [NU]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches**

9021T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1672.95	31.60	PKU Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL bottles**

9396M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1041.75	31.60	PKU Anamix Junior LQ [SB]

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 28 g sachets**

12136R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1672.95	31.60	PKU Lophlex [SB]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouches**

8846N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1270.11	31.60	PKU Cooler 15 [VF]

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

10411Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1692.27	31.60	PKU Air 20 [VF]



**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2474F	4	5	..	*1692.27	31.60	PKU Cooler 20 [VF]

NP

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8746H	5	5	..	*852.52	31.60	Easiphen [SB]

NP

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9397N	2	5	..	*680.69	31.60	PKU Lophlex LQ 10 [SB]

NP

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2382J	4	5	..	*849.63	31.60	PKU Cooler 10 [VF]

NP

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2739E	8	5	..	*1109.55	31.60	XP Maxamum [SB]

NP

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8591E	4	5	..	*1270.79	31.60	PKU express 15 [VF]

NP

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 34 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1909L	4	5	..	*1692.27	31.60	PKU express 20 [VF]

NP

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE****Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10258X	4	5	..	*869.51	31.60	PKU Anamix Junior [SB]

NP

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE****Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2701E	4	5	..	*3359.63	31.60	TYR cooler 20 [VF]

NP

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 28 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12274B	4	5	..	*3359.63	31.60	TYR Lophlex [SB]

NP

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8445L	8	5	..	*634.11	31.60	TYR Anamix infant [SB]

NP

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 125 mL pouches**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1547K	3	5	..	*2023.56	31.60	TYR Lophlex LQ 20 [SB]

NP

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE****Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.**Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets**

10260B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1743.79	31.60	TYR Anamix Junior [SB]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID****Restricted benefit**

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

14126L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*1743.79	31.60	TYR explore5 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE****Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches**

2654Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*3359.63	31.60	MSUD cooler 20 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 28 g sachets**

12285N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*3359.63	31.60	MSUD Lophlex [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g**

2380G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*634.11	31.60	MSUD Anamix infant [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 125 mL pouches**

1546J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	3	5	..	*2560.35	31.60	MSUD Lophlex LQ 20 [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL pouches**

2375B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*2560.39	31.60	MSUD cooler 15 [VF]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

8057C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*2240.67	31.60	MSUD Maxamum [SB]

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets**

8632H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*2560.39	31.60	MSUD express 15 [VF]

**■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE****Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.**Restricted benefit**

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets**

10259Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1743.79	31.60	MSUD Anamix Junior [SB]

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9499Y	4	5	..	*1632.11	31.60	MSUD Anamix Junior LQ [SB]

NP

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14118C	8	5	..	*1743.79	31.60	MSUD explore5 [VF]

NP

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID**

**Restricted benefit**

Phenylketonuria

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11836Y	4	5	..	*957.75	31.60	PKU Explore 10 [VF]

NP

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11185Q	8	5	..	*957.71	31.60	PKU Anamix First Spoon [SB]

NP

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11859E	8	5	..	*957.71	31.60	PKU Explore 5 [VF]

NP

■ **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14114W	8	5	..	*1743.79	31.60	HCU explore5 [VF]

NP

■ **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8479G	8	5	..	*580.19	31.60	PKU Anamix infant [SB]

NP

■ **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

**Note** The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

**Restricted benefit**

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 4 x 400 g**

14239K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*616.67	31.60	PKU Start [VF]

#### ■ AMINO ACID FORMULA WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

**amino acid formula without phenylalanine 1 g tablet, 75**

8678R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*1170.75	31.60	Phlexy-10 [SB]

#### ■ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

**amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 6 g sachets**

10161T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	12	5	..	*2826.87	31.60	MSUD amino5 [VF]

#### ■ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

**arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid powder for oral liquid, 30 x 4 g sachets**

10036F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*336.71	31.60	keyomega [VF]

#### ■ ARGININE WITH CARBOHYDRATE

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

**arginine with carbohydrate containing 500 mg arginine powder for oral liquid, 30 x 4 g sachets**

9437Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*448.35	31.60	Arginine 500 [VF]

**arginine with carbohydrate containing 5 g arginine powder for oral liquid, 30 x 7.6 g sachets**

10093F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*881.59	31.60	Arginine 5000 [VF]

**arginine with carbohydrate containing 2 g arginine powder for oral liquid, 30 x 4 g sachets**

5482M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*668.31	31.60	Arginine 2000 [VF]

#### ■ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

Restricted benefit

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g**

8369L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*259.07	31.60	Energivit [SB]

#### ■ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets**

10039J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*432.79	31.60	basecal 200 [VF]

## ■ CITRULLINE

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

### Restricted benefit

Urea cycle disorders

### **Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline 1 g tablet, 300**

10736C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	1144.94	31.60	Citrulline Easy [OH]

## ■ CITRULLINE WITH CARBOHYDRATE

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

### Restricted benefit

Urea cycle disorders

### **Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets**

5481L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*448.35	31.60	Citrulline 1000 [VF]

## ■ ESSENTIAL AMINO ACIDS FORMULA

### Restricted benefit

Gyrate atrophy of the choroid and retina

### Restricted benefit

Urea cycle disorders

**essential amino acids formula powder for oral liquid, 2 x 200 g**

9329B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1033.29	31.60	Essential Amino Acid Mix [SB]

## ■ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

### Restricted benefit

Gyrate atrophy of the choroid and retina

### Restricted benefit

Urea cycle disorders

**essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

2027Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*523.27	31.60	Dialamine [SB]

## ■ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

### Restricted benefit

Gyrate atrophy of the choroid and retina

### Restricted benefit

Urea cycle disorders

**essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets**

13759E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1181.97	31.60	EAA Supplement [VF]

## ■ GLYCINE WITH CARBOHYDRATE

### Restricted benefit

Isovaleric acidaemia

**glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets**

10195N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*472.79	31.60	Glycine500 [VF]

## ■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE

### Restricted benefit

Tyrosinaemia

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 35 g sachets**

11832R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*3901.83	31.60	TYR Sphere20 [VF]

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 31 g sachets**

12175T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*3199.79	31.60	Tylactin Build 20 [QH]

## ■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

### Restricted benefit

Tyrosinaemia

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g**

11290F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*2780.03	31.60	Tylactin Complete [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

10528D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*2967.03	31.60	Tylactin RTD [QH]

## ■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

### Restricted benefit

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 40 g sachets**

13714T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1580.39	31.60	Camino Pro Bettermilk [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

2644E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	14	5	..	*1294.43	31.60	Camino Pro Complete [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets**

11084J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	5	..	*1317.87	31.60	PKU Restore [QH]

## ■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

### Restricted benefit

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

10332T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1580.35	31.60	PKU Glytactin RTD 15 [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

11640P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*1580.35	31.60	PKU Glytactin RTD 15 Lite [QH]

## ■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.

### Restricted benefit

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11287C	2	5	..	*1075.35	31.60	PKU Build 10 [QH]

**glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11279P	4	5	..	*2085.39	31.60	PKU Build 20 [QH]

■ **GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS AND LOW PHENYLALANINE**

**Note** This product does not contain any vitamins, is low in mineral content and is not intended as a sole source of nutrition.

**Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with amino acids and low phenylalanine powder for oral liquid, 30 x 12.5 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14650C	5	5	..	*1317.87	31.60	PKU GMPPro MIX-IN [SB]

■ **GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine powder for oral liquid, 30 x 33.4 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14644R	4	5	..	*2085.39	31.60	PKU GMPPro ULTRA [SB]

■ **GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11071Q	4	5	..	*1984.39	31.60	PKU Sphere20 [VF]

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 15 x 237 mL bottles**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13257R	8	5	..	*1984.43	31.60	PKU Sphere Liquid [VF]

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11245W	4	5	..	*1504.63	31.60	PKU Sphere15 [VF]

■ **GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Restricted benefit**

Phenylketonuria

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11844J	10	5	..	*1504.57	31.60	PKU GMPPro LQ [SB]

■ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Note** Requests seeking an increased maximum quantity (packs) up to 4 times that stated, may be authorised.

**Restricted benefit**

Ketogenic diet

**Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR

- Patient must have pyruvate dehydrogenase deficiency.

#### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs

12635B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*794.79	31.60	K.Yo [VF]

#### ■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

##### Restricted benefit

Ketogenic diet

##### **Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

#### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

10185C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*940.02	31.60	KetoCal 4:1 LQ [SB]

#### ■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

##### Restricted benefit

Ketogenic diet

##### **Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

##### **Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

#### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

12456N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1022.61	31.60	KetoVie 4:1 [QH]

#### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

12464B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*695.37	31.60	KetoVie 3:1 [QH]

#### ■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

##### Restricted benefit

Ketogenic diet

##### **Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

#### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g

2652N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*840.27	31.60	KetoCal 3:1 [SB]

#### ■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.



**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g

9446E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*878.19	31.60	KetoCal 4:1 [SB]

## ■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency, **AND**
  - Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula, **AND**
  - Patient must have unsuccessfully trialed at least one of the PBS-listed products with the indication of: 'Ketogenic diet'.
- This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

### high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons

12789D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	6	5	..	*1155.45	31.60	KetoVie Peptide 4:1 [QH]

## ■ ISOLEUCINE WITH CARBOHYDRATE

**Restricted benefit**

Maple syrup urine disease

### isoleucine with carbohydrate containing 1 g isoleucine powder for oral liquid, 30 x 4 g sachets

9436P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*492.35	31.60	Isoleucine 1000 [VF]

### isoleucine with carbohydrate containing 50 mg isoleucine powder for oral liquid, 30 x 4 g sachets

9134R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*448.35	31.60	Isoleucine 50 [VF]

## ■ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

### milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g

8630F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*909.63	31.60	Carbohydrate Free Mixture [SB]

## ■ PHENYLALANINE WITH CARBOHYDRATE

**Restricted benefit**

Tyrosinaemia

### phenylalanine with carbohydrate containing 50 mg phenylalanine powder for oral liquid, 30 x 4 g sachets

9384X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*448.35	31.60	Phenylalanine 50 [VF]

## ■ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

### Restricted benefit

Phenylketonuria

protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches

10658Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	5	5	..	*1826.67	31.60	PKU Easy [OH]

## ■ PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A

### Authority required (STREAMLINED)

11070

Chronic renal failure

### Population criteria:

- Patient must be a child aged 3 years or older.

### Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A oral liquid, 24 x 125 mL bottles

12191P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*1329.55	31.60	Renastep [VF]

## ■ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

### Restricted benefit

Ketogenic diet

### Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can

8577K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	120	5	..	*552.27	31.60	RCF [AB]

## ■ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

### Restricted benefit

Proven inborn errors of protein metabolism

### Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons

10189G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*120.29	31.60	Sno-Pro [SB]

triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons

9309Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*713.71	31.60	ProZero [VF]

## ■ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

### Restricted benefit

Proven inborn errors of protein metabolism

### Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g

3136C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*239.71	31.60	Duocal [SB]

## ■ TYROSINE WITH CARBOHYDRATE

**Note** This formulation is suitable for patients aged 3 and older.

### Restricted benefit

Phenylketonuria

**tyrosine with carbohydrate containing 1 g tyrosine powder for oral liquid, 30 x 4 g sachets**

9165J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*448.35	31.60	Tyrosine 1000 [VF]

**■ VALINE WITH CARBOHYDRATE****Restricted benefit**

Maple syrup urine disease

**valine with carbohydrate containing 1 g valine powder for oral liquid, 30 x 4 g sachets**

9434M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*492.35	31.60	Valine 1000 [VF]

**valine with carbohydrate containing 50 mg valine powder for oral liquid, 30 x 4 g sachets**

9135T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*448.35	31.60	Valine 50 [VF]

**■ VITAMINS, MINERALS AND TRACE ELEMENTS****Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets**

11200L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	282.27	31.60	Phlexy-Vits [SB]

**■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE****Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets**

10149E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	254.88	31.60	FruitiVits [VF]

**■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE****Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be an infant or a child.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g**

9328Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*336.99	31.60	Paediatric Seravit [SB]

▪ **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required (STREAMLINED)**

**6190**

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans**

2870C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1364.55	31.60	Renastart [VF]

▪ **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required (STREAMLINED)**

**6190**

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

8587Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	16	5	..	*874.43	31.60	Kindergen [SB]

# Palliative Care

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## ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Other agents for local oral treatment*

#### BENZYDAMINE

**Authority required (STREAMLINED)**

**6197**

Painful mouth

**Clinical criteria:**

- Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

5385K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	22.17	23.62	Difflam [IL]

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**Authority required (STREAMLINED)**

**6207**

For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

5317W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	3	..	*55.83	31.60	<sup>a</sup> Buscopan [VZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE-AFT [AE]
						<sup>a</sup> HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE SXP [XN]

### PROPULSIVES

*Propulsives*

#### METOCLOPRAMIDE

**Authority required (STREAMLINED)**

**6084**

Nausea or gastric stasis

**Clinical criteria:**

- Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

10762K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	2	..	*43.99	31.60	<sup>a</sup> Metoclopramide HCl Medsurge [DZ]	<sup>a</sup> METOCLOPRAMIDE INJECTION BP [WZ]

#### METOCLOPRAMIDE

**Restricted benefit**

For use in patients receiving palliative care

**metoclopramide hydrochloride 10 mg tablet, 25**

12507G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*24.23	25.68	<sup>a</sup> APO-Metoclopramide [TX]	<sup>a</sup> EMEXLON [RW]
						<sup>a</sup> METOCLOPRAMIDE-WGR [WG]	<sup>a</sup> Pramin [AF]
			<sup>B</sup> 14.20	*38.43	25.68	<sup>a</sup> Maxolon [IL]	

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Osmotically acting laxatives*

#### MACROGOL-3350

**Authority required (STREAMLINED)**

**6170**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

5426N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*32.41	31.60	OsmoLax [KY]

**MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**Authority required (STREAMLINED)**6171**

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets**

5389P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*26.01	27.46	<sup>a</sup> APOHEALTH Macrogol with Electrolytes [GX] <sup>a</sup> Chemists' Own Macrogol with Electrolytes [RW] <sup>a</sup> Molaxole [XT]	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES [TX] <sup>a</sup> Macrovic [RF]

*Enemas***CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL**Restricted benefit

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

5331N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*37.21	31.60	Micolette [AE]

*Peripheral opioid receptor antagonists***METHYLNALTREXONE**Authority required (STREAMLINED)**6180**

Opioid-induced constipation

**Clinical criteria:**

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

**methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial**

5423K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	..	..	*183.25	31.60	Relistor [LM]

**methylnaltrexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials**

5424L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	183.26	31.60	Relistor [LM]

**MUSCULO-SKELETAL SYSTEM****ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS****ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS***Acetic acid derivatives and related substances***INDOMETACIN**Restricted benefit

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

**indometacin 25 mg capsule, 50**

5377B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*20.13	21.58	<sup>a</sup> Arthrexin [AF]
			<sup>B</sup> 4.04	*24.17	21.58	<sup>a</sup> Indocid [AS]

## NERVOUS SYSTEM

### Propionic acid derivatives

#### ■ IBUPROFEN

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

##### ibuprofen 400 mg tablet, 30

5368M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	3	..	*21.54	22.99	<sup>a</sup> APO-Ibuprofen 400 [TX]	<sup>a</sup> WGR-IBUPROFEN 400 [WG]
			<sup>B</sup> 7.53	*29.07	22.99	<sup>a</sup> Brufen [GO]	

#### ■ NAPROXEN

##### Restricted benefit

Severe pain

##### Treatment criteria:

- Patient must be undergoing palliative care.

##### Clinical criteria:

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

##### naproxen 125 mg/5 mL oral liquid, 474 mL

5397C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	124.15	31.60	Phebra Naproxen Suspension [FF]

#### ■ NAPROXEN

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

##### naproxen 1 g modified release tablet, 28

5348L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	20.02	21.47	<sup>a</sup> Proxen SR 1000 [IY]
			<sup>B</sup> 2.35	22.37	21.47	<sup>a</sup> Naprosyn SR1000 [IX]

##### naproxen 250 mg tablet, 50

5345H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*22.91	24.36	Naprosyn [IX]

##### naproxen 750 mg modified release tablet, 28

5347K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.41	19.86	<sup>a</sup> Proxen SR 750 [IY]
			<sup>B</sup> 2.35	20.76	19.86	<sup>a</sup> Naprosyn SR750 [IX]

#### ■ NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

##### Restricted benefit

Severe pain

##### Clinical criteria:

- Patient must be receiving palliative care.

##### naproxen sodium 550 mg tablet, 50

5353R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	19.02	20.47	<sup>a</sup> Crysanal [IY]
			<sup>B</sup> 2.85	21.87	20.47	<sup>a</sup> Anaprox 550 [IX]

## ■ NERVOUS SYSTEM

## ■ ANALGESICS

### OPIOIDS

#### Natural opium alkaloids

#### ■ HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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**Authority required (STREAMLINED)****11697**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

12531M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	1	..	*35.02	31.60	<sup>a</sup> Dilaudid-HP [MF]	<sup>a</sup> Hydromorphone-hameln-HP [HW]
						<sup>a</sup> HYDROMORPHONE JUNO-HP [JU]	<sup>a</sup> MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ]

**hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

12493M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	1	..	*30.96	31.60	<sup>a</sup> Dilaudid [MF]	<sup>a</sup> Hydromorphone-hameln [HW]
						<sup>a</sup> HYDROMORPHONE JUNO [JU]	<sup>a</sup> MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ]

**hydromorphone hydrochloride 2 mg tablet, 20**

12497R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*32.02	31.60	Dilaudid [MF]

**hydromorphone hydrochloride 4 mg tablet, 20**

12484C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*36.56	31.60	Dilaudid [MF]

**hydromorphone hydrochloride 8 mg tablet, 20**

12515Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*53.38	31.60	Dilaudid [MF]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL**

14084G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	435.42	31.60	pms-HYDROMORPHONE [DZ]

**■ HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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**Note** Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

**Authority required (STREAMLINED)****11697**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

12565H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	434.30	31.60	<sup>a</sup> Hikma [LM]

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

13806P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	435.42	31.60	<sup>a</sup> Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate pentahydrate 30 mg tablet, 20**

14655H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	30.41	31.60	Anamorph [RW]

**morphine sulfate pentahydrate 10 mg tablet, 20**

5393W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	23.35	24.80	Sevredol [MF]

**morphine sulfate pentahydrate 20 mg tablet, 20**

5394X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	24.10	25.55	Sevredol [MF]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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[Your capital city]

**Authority required (STREAMLINED)**

**11697**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate 2 mg/mL oral solution, 100 mL**

13743H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	1	..	*493.94	31.60	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

**morphine sulfate 2 mg/mL oral solution, 500 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13748N NP	4	1	..	*447.52	31.60	Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL) [DZ]

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12494N NP	2	1	..	*31.50	31.60	Morphine Juno [JU]

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12548K NP	2	1	..	*34.28	31.60	MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12503C NP	2	1	..	*38.48	31.60	MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

**morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12470H NP	2	1	..	*43.10	31.60	Morphine Juno [JU]

**morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12537W NP	2	1	..	*55.20	31.60	Morphine Juno [JU]

**morphine sulfate 10 mg/5 mL oral solution, 100 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13742G NP	10	1	..	*688.34	31.60	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

**morphine sulfate 10 mg/5 mL oral solution, 300 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13741F NP	7	1	..	*724.68	31.60	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL [LM]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand Morphine HCl Streuli or the brand RA-Morph (NZ) can be substituted for pharmaceutical benefits that have the brand Ordine 10 in case of a shortage.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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**Authority required (STREAMLINED)**

**11697**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12472K NP	2	1	..	*296.08	31.60	<sup>a</sup> Ordine 10 [XT]

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14187Q	2	1	..	*296.08	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14081D	20	1	..	*1119.04	31.60	<sup>a</sup> Morphini HCl Streuli [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
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[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 30 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12500X	2	..	..	*53.82	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX]	<sup>a</sup> Morphine MR Mylan [AF]
						<sup>a</sup> MS Contin [MF]	

**morphine sulfate pentahydrate 5 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12492L	2	..	..	*32.38	31.60	MS Contin [MF]

**morphine sulfate pentahydrate 60 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12544F	2	..	..	*80.26	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX]	<sup>a</sup> Morphine MR Mylan [AF]
						<sup>a</sup> MS Contin [MF]	

**morphine sulfate pentahydrate 10 mg modified release capsule, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12501Y	2	..	..	*37.80	31.60	Kapanol [YN]

**morphine sulfate pentahydrate 100 mg modified release capsule, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12529K	2	..	..	*102.68	31.60	Kapanol [YN]

**morphine sulfate pentahydrate 120 mg modified release capsule, 14**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12512M	2	..	..	*80.24	31.60	MS Mono [MF]

**morphine sulfate pentahydrate 20 mg modified release capsule, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12539Y	2	..	..	*39.60	31.60	Kapanol [YN]

**morphine sulfate pentahydrate 30 mg modified release capsule, 14**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12490J	2	..	..	*38.56	31.60	MS Mono [MF]

**morphine sulfate pentahydrate 50 mg modified release capsule, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12489H	2	..	..	*63.52	31.60	Kapanol [YN]

**morphine sulfate pentahydrate 60 mg modified release capsule, 14**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12487F	2	..	..	*53.78	31.60	MS Mono [MF]

**morphine sulfate pentahydrate 90 mg modified release capsule, 14**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12514P	2	..	..	*61.08	31.60	MS Mono [MF]

**morphine sulfate pentahydrate 10 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12547J	2	..	..	*33.12	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX]	<sup>a</sup> Morphine MR Mylan [AF]
						<sup>a</sup> MS Contin [MF]	

**morphine sulfate pentahydrate 100 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12483B	2	..	..	*105.48	31.60	<sup>a</sup> MORPHINE MR APOTEX [TX]	<sup>a</sup> Morphine MR Mylan [AF]
						<sup>a</sup> MS Contin [MF]	

**morphine sulfate pentahydrate 15 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12476P	2	..	..	*45.10	31.60	MS Contin [MF]

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5391R	2	..	..	*229.04	31.60	MS Contin [MF]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

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Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)**

**11697**

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12502B	2	1	..	*27.12	28.57	<sup>a</sup> Morphine Juno [JU]

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12499W	2	1	..	*28.76	30.21	<sup>a</sup> MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

**■ MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the brand RA-Morph (NZ) can be substituted for Ordine 5 in case of shortage.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
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[Your capital city]

#### Authority required (STREAMLINED)

**11697**

Severe pain

#### Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

#### Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12549L	2	1	..	*194.48	31.60	<sup>a</sup> Ordine 5 [XT]

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14186P	2	1	..	*194.48	31.60	<sup>a</sup> RA-Morph (NZ) [WZ]

### ■ MORPHINE

**Caution** The risk of drug dependence is high.

Morphine sulfate pentahydrate 10 and 20 mg modified release capsules must not be co-prescribed with immediate release oral morphine, when it has been prescribed for the reduction of chronic breathlessness.

**Note** Treatment should be initiated by a specialist knowledgeable in the use of potent opioids for the management of chronic breathlessness.

**Note** Applications for an increased maximum quantity to provide for 1 month's supply of this drug will be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

#### Restricted benefit

Chronic Breathlessness

#### Clinical criteria:

- Patient must be receiving palliative care.

#### morphine sulfate pentahydrate 10 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11760Y	1	..	..	28.31	29.76	Kapanol [YN]

#### morphine sulfate pentahydrate 20 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11761B	1	..	..	29.21	30.66	Kapanol [YN]

### ■ OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

#### Authority required

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg modified release tablet, 28**

12518W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*40.84	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 15 mg modified release tablet, 28**

12545G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*57.32	31.60	OxyContin [MF]

**oxycodone hydrochloride 20 mg modified release tablet, 28**

12510K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*57.80	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 30 mg modified release tablet, 28**

12538X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*84.48	31.60	OxyContin [MF]

**oxycodone hydrochloride 40 mg modified release tablet, 28**

12525F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*77.76	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**oxycodone hydrochloride 80 mg modified release tablet, 28**

12527H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*115.38	31.60	<sup>a</sup> Oxycodone Sandoz [SZ]	<sup>a</sup> OxyContin [MF]

**■ OXYCODONE + NALOXONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

12511L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*151.64	31.60	Targin 60/30 [MF]

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

12498T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*158.96	31.60	Targin 80/40 [MF]

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

12471J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*38.56	31.60	Targin 2.5/1.25 mg [MF]

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

12540B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*65.00	31.60	Targin 15/7.5mg [MF]

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

12532N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*97.58	31.60	Targin 30/15 mg [MF]

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

12523D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*56.30	31.60	Targin 10/5mg [MF]

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

12486E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*85.28	31.60	Targin 20/10mg [MF]

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

12475N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*119.30	31.60	Targin 40/20mg [MF]

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

12522C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*54.04	31.60	Targin 5/2.5mg [MF]

*Phenylpiperidine derivatives***■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 400 microgram sublingual tablet, 10**

10603C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	81.71	31.60	Abstral [FK]

**fentanyl 100 microgram sublingual tablet, 10**

10601Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*145.88	31.60	Abstral [FK]

**fentanyl 200 microgram sublingual tablet, 10**

10600X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*145.88	31.60	Abstral [FK]

**fentanyl 200 microgram lozenge, 9**

5401G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	90.40	31.60	Actiq [TB]

**fentanyl 400 microgram lozenge, 9**

5402H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	90.40	31.60	Actiq [TB]



**fentanyl 100 microgram orally disintegrating tablet, 4**

10729Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*77.34	31.60	Fentora [TB]

**fentanyl 200 microgram orally disintegrating tablet, 4**

10697B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*77.34	31.60	Fentora [TB]

**fentanyl 300 microgram sublingual tablet, 10**

10606F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	81.71	31.60	Abstral [FK]

**fentanyl 600 microgram sublingual tablet, 10**

10604D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	81.71	31.60	Abstral [FK]

**fentanyl 800 microgram sublingual tablet, 10**

10612M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	81.71	31.60	Abstral [FK]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 months' therapy.

**Authority required**

Breakthrough pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**fentanyl 100 microgram sublingual tablet, 30**

10602B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

**fentanyl 200 microgram sublingual tablet, 30**

10607G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

**fentanyl 400 microgram sublingual tablet, 30**

10608H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

**fentanyl 200 microgram lozenge, 30**

5407N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*514.78	31.60	Actiq [TB]

**fentanyl 400 microgram lozenge, 30**

5408P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*514.78	31.60	Actiq [TB]

**fentanyl 600 microgram lozenge, 30**

5409Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*377.58	31.60	Actiq [TB]

**fentanyl 800 microgram lozenge, 30**

5410R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*377.58	31.60	Actiq [TB]

**fentanyl 200 microgram orally disintegrating tablet, 28**

10698C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*443.74	31.60	Fentora [TB]

**fentanyl 400 microgram orally disintegrating tablet, 28**

10737D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*285.36	31.60	Fentora [TB]

**fentanyl 600 microgram orally disintegrating tablet, 28**

10713W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*285.36	31.60	Fentora [TB]

**fentanyl 800 microgram orally disintegrating tablet, 28**

10738E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*285.36	31.60	Fentora [TB]

**fentanyl 100 microgram orally disintegrating tablet, 28**

10684H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*443.74	31.60	Fentora [TB]

**fentanyl 300 microgram sublingual tablet, 30**

10610K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

**fentanyl 600 microgram sublingual tablet, 30**

10613N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

**fentanyl 800 microgram sublingual tablet, 30**

10611L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*409.96	31.60	Abstral [FK]

■ **FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 75 microgram/hour patch, 5**

12474M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*51.96	31.60	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 75 [JC]

**fentanyl 75 microgram/hour patch, 5**

12517T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*59.78	31.60	<sup>a</sup> Fenpatch 75 [RW]

**fentanyl 75 microgram/hour patch, 5**

12526G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*51.96	31.60	<sup>a</sup> Denpax [AF]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
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**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 50 microgram/hour patch, 5**

12477Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*43.02	31.60	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 50 [JC]

**fentanyl 50 microgram/hour patch, 5**

12513N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*48.70	31.60	<sup>a</sup> Fenpatch 50 [RW]

**fentanyl 50 microgram/hour patch, 5**

12546H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*43.02	31.60	<sup>a</sup> Denpax [AF]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
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**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 100 microgram/hour patch, 5**

12480W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*69.20	31.60	<sup>a</sup> Fenpatch 100 [RW]

**fentanyl 100 microgram/hour patch, 5**

12509J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*59.94	31.60	<sup>a</sup> APO-Fentanyl [TX]	<sup>a</sup> Durogesic 100 [JC]
						<sup>a</sup> Fentanyl Sandoz [SZ]	

**fentanyl 100 microgram/hour patch, 5**

12533P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*59.94	31.60	<sup>a</sup> Denpax [AF]

**■ FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 12 microgram/hour patch, 5**

12491K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*29.18	30.63	<sup>a</sup> Denpax [AF]

**fentanyl 12 microgram/hour patch, 5**

12530L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*31.62	31.60	<sup>a</sup> Fenpatch 12 [RW]

**fentanyl 12 microgram/hour patch, 5**

12541C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*29.18	30.63	<sup>a</sup> APO-Fentanyl [TX]	<sup>a</sup> Durogesic 12 [JC]
						<sup>a</sup> Fentanyl Sandoz [SZ]	

## ■ FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

### **Authority required**

Severe disabling pain

### **Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

### **Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### **fentanyl 25 microgram/hour patch, 5**

12504D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*32.00	31.60	<sup>a</sup> APO-Fentanyl [TX] <sup>a</sup> Fentanyl Sandoz [SZ]	<sup>a</sup> Durogesic 25 [JC]

### **fentanyl 25 microgram/hour patch, 5**

12516R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*32.00	31.60	<sup>a</sup> Denpax [AF]

### **fentanyl 25 microgram/hour patch, 5**

12521B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	..	..	*35.10	31.60	<sup>a</sup> Fenpatch 25 [RW]

### *Diphenylpropylamine derivatives*

## ■ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

### **Authority required**

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

### **Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

### **methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5399E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	27.33	28.78	Aspen Methadone Syrup [AS]

## ■ METHADONE

**Caution** The risk of drug dependence is high.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Telephone approvals are limited to 1 month's therapy.

### **Authority required**

Chronic severe disabling pain

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

5400F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	27.33	28.78	Aspen Methadone Syrup [AS]

**■ METHADONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**methadone hydrochloride 10 mg tablet, 20**

12520Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	6	..	..	*50.64	31.60	<sup>a</sup> METHADONE-AFT [AE]	<sup>a</sup> Physeptone [AS]

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials**

14193B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	..	..	*906.84	31.60	Physeptone [AS]

***Oripavine derivatives*****■ BUPRENORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos](http://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)).  
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  
Pharmaceutical Benefits Scheme  
Reply Paid 9857  
[Your capital city]

**Authority required**

Severe disabling pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**buprenorphine 15 microgram/hour patch, 2**

10953L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*53.34	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 25 microgram/hour patch, 2**

10964C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*67.68	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 30 microgram/hour patch, 2**

10949G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*74.64	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 40 microgram/hour patch, 2**

10959T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*88.62	31.60	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]	<sup>a</sup> Buprenorphine Sandoz [SZ]

**buprenorphine 10 microgram/hour patch, 2**

10948F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*45.98	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 20 microgram/hour patch, 2**

10970J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*60.70	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**buprenorphine 5 microgram/hour patch, 2**

10957Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*33.92	31.60	<sup>a</sup> B-Patch [IU] <sup>a</sup> Buprenorphine Sandoz [SZ]	<sup>a</sup> Bupredermal [TX] <sup>a</sup> Norspan [MF]

**OTHER ANALGESICS AND ANTIPYRETICS***Anilides***■ PARACETAMOL****Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 500 mg suppository, 10**

12210P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*98.47	31.60	Panadol [GJ]

**■ PARACETAMOL**

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Analgesia or fever

**Clinical criteria:**

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

**paracetamol 665 mg modified release tablet, 96**

5343F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*20.99	22.44	<sup>a</sup> APOHEALTH Osteo Relief Paracetamol 665 mg [TX] <sup>a</sup> Parapane OSTEO [XT]	<sup>a</sup> Osteomol 665 Paracetamol [CR]

**paracetamol 665 mg modified release tablet, 192**

10796F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	20.99	22.44	<sup>a</sup> Osteomol 665 Paracetamol [CR]	<sup>a</sup> Parapane OSTEO [XT]

## ■ ANTIEPILEPTICS

### ANTIEPILEPTICS

#### *Benzodiazepine derivatives*

## ■ CLONAZEPAM

### Restricted benefit

For use in patients receiving palliative care

#### clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

12534Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	1	..	24.03	25.48	Rivotril [PB]

## ■ CLONAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

For use in patients receiving palliative care

#### clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

5339B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*20.99	22.44	Rivotril [PB]

#### clonazepam 2 mg tablet, 100

5338Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	22.95	24.40	Paxam 2 [AF]

## ■ CLONAZEPAM

**Note** Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

### Restricted benefit

For use in patients receiving palliative care

#### clonazepam 500 microgram tablet, 50

11520H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	3	<sup>B</sup> 1.84	*22.09	21.70	<sup>a</sup> Rivotril [PB]

#### clonazepam 500 microgram tablet, 100

5337X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	3	..	20.23	21.68	<sup>a</sup> Paxam 0.5 [AF]

## ■ PSYCHOLEPTICS

### ANTIPSYCHOTICS

#### *Butyrophenone derivatives*

## ■ HALOPERIDOL

### Restricted benefit

For use in patients receiving palliative care

#### haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

12519X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	24.66	26.11	Serenace [AS]

### ANXIOLYTICS

#### *Benzodiazepine derivatives*

## ■ DIAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Anxiety

### Clinical criteria:

- Patient must be receiving palliative care.

#### diazepam 2 mg tablet, 50

5355W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	16.37	17.82	<sup>a</sup> APX-Diazepam [TY] <sup>a</sup> Valpam 2 [RW]	<sup>a</sup> DIAZEPAM-WGR [WG]



			<sup>B</sup> 2.78	19.15	17.82	<sup>a</sup> Antenex 2 [AF]	
<b>diazepam 5 mg tablet, 50</b>							
5356X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1	3	..	16.37	17.82	<sup>a</sup> Antenex 5 [AF] <sup>a</sup> DIAZEPAM-WGR [WG] <sup>a</sup> Valpam 5 [RW]	<sup>a</sup> APX-Diazepam [TY] <sup>a</sup> NOUMED DIAZEPAM [VO]
			<sup>B</sup> 3.08	19.45	17.82	<sup>a</sup> Valium [IX]	

## ■ OXAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Anxiety

### **Clinical criteria:**

- Patient must be receiving palliative care.

### **oxazepam 15 mg tablet, 25**

5371Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*18.89	20.34	<sup>a</sup> Alepam 15 [AF]	<sup>a</sup> Serepax [AS]

### **oxazepam 30 mg tablet, 25**

5372R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*18.89	20.34	<sup>a</sup> Alepam 30 [AF] <sup>a</sup> OXAZEPAM-WGR [WG]	<sup>a</sup> APO-Oxazepam [TX]
			<sup>B</sup> 1.68	*20.57	20.34	<sup>a</sup> Murelax [RW]	
			<sup>B</sup> 7.84	*26.73	20.34	<sup>a</sup> Serepax [AS]	

## HYPNOTICS AND SEDATIVES

### *Benzodiazepine derivatives*

## ■ NITRAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Insomnia

### **Clinical criteria:**

- Patient must be receiving palliative care.

### **nitrazepam 5 mg tablet, 25**

5359C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*18.89	20.34	<sup>a</sup> Alodorm [AF]	<sup>a</sup> Mogadon [IL]

## ■ TEMAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Insomnia

### **Clinical criteria:**

- Patient must be receiving palliative care.

### **temazepam 10 mg tablet, 25**

5375X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	3	..	*18.89	20.34	<sup>a</sup> APO-Temazepam [TX] <sup>a</sup> TEMAZEPAM-WGR [WG]	<sup>a</sup> Temaze [AF] <sup>a</sup> Temtabs [LN]
			<sup>B</sup> 10.14	*29.03	20.34	<sup>a</sup> Normison [AS]	

# Repatriation Pharmaceutical Benefits Scheme

## BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

### Gold card

This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

### White card

A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

### Orange card

Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.



For more information go to the Department of Veterans' Affairs website:  
<http://www.dva.gov.au>

# RPBS Explanatory Notes

## Introduction

### *The Australian Repatriation System*

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

### RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

### *Prior Approval Arrangements*

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

### *Palliative Care Drugs*

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine

- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide
- For further information telephone VAPAC on 1800 552 580.

### **Dental Prescribing**

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

### **Prescribing by optometrists**

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

## **Provisions governing pricing and payment for RPBS benefits**

### **Introduction**

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

### **Pricing of Schedule Items**

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

### **Pricing of Non-Schedule Ready Prepared Items**

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than \$100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

### **Pricing of Non-Schedule Extemporaneously Prepared Items**

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

### **Miscellaneous Pricing Rules**

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

## General

### **Packaging Material, Postage or Freight**

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacist's itemised receipt.

### **Payment for Items Supplied at Short Intervals**

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

### **Receipts for Patient Charges**

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patient's name and address. The patient may apply for reimbursement from the Department.

### **Special Patient Contributions**

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

### **Therapeutic Group Premiums — Authority Processing**

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

## Contact the Department of Veterans' Affairs

### **Authority Prescription Applications**

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998

VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

**For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580**

**Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.**

## WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

### DRESSINGS

#### Pink Epithelialising Wound

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	<ul style="list-style-type: none"> <li>Film;</li> <li>Film Island</li> </ul>	<ul style="list-style-type: none"> <li>Gauze—Paraffin;</li> <li>Non-adherent</li> </ul>
(B) Absorbing	<ul style="list-style-type: none"> <li>Foam (Light Exudate);</li> <li>Hydroactive (Superficial Wound—Light Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>Hydrocolloid (Superficial Wound—Light Exudate)</li> </ul>

#### Red Granulating Wound

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>Foam (Light Exudate);</li> <li>Hydroactive (Superficial Wound—Light Exudate);</li> <li>Hydrocolloid (Superficial Wound—Light Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	<ul style="list-style-type: none"> <li>Hydrogel—Amorphous;</li> <li>Hydrogel—Sheet</li> </ul>	<ul style="list-style-type: none"> <li>Hydrogel—Amorphous</li> </ul>
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>Alginate (Superficial Wound);</li> <li>Foam—Heavy Exudate;</li> <li>Hydroactive (Superficial Wound—Moderate Exudate);</li> <li>Hydrocolloid (Superficial Wound—Moderate/High Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>Alginate (Cavity Wound);</li> <li>Foam—Moderate Exudate (see “cavity conforming” product);</li> <li>Hydroactive (Cavity Wound);</li> <li>Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	NOT APPROPRIATE	

#### Yellow Sloughy Wound

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>Cadexomer Iodine;</li> <li>Foam—Light Exudate;</li> <li>Foam with Charcoal;</li> <li>Hydroactive (Superficial Wound—Moderate Exudate);</li> <li>Hydrocolloid (Superficial Wound—Moderate Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>Cadexomer Iodine;</li> <li>Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture Donating	<ul style="list-style-type: none"> <li>Hydrogel—Amorphous;</li> <li>Hydrogel—Sheet</li> </ul>	<ul style="list-style-type: none"> <li>Hydrogel—Amorphous</li> </ul>
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"> <li>Alginate (Superficial Wound);</li> <li>Cadexomer Iodine;</li> <li>Foam—Heavy Exudate;</li> <li>Hydroactive (Superficial Wound—Moderate/High Exudate);</li> <li>Hydrocolloid (Superficial Wound—Moderate/High Exudate)</li> </ul>	<ul style="list-style-type: none"> <li>Alginate (Cavity Wound);</li> <li>Cadexomer Iodine;</li> <li>Hydrocolloid (Cavity Wound)</li> </ul>
(B) Moisture donating	NOT APPROPRIATE	

### Black Necrotic Wound

Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	<ul style="list-style-type: none"><li>• Hydroactive (Superficial Wound—Light Exudate);</li><li>• Hydrocolloid (Superficial Wound—Light/Moderate Exudate)</li></ul>	<ul style="list-style-type: none"><li>• Hydrocolloid (Cavity Wound)</li></ul>
(B) Moisture donating	<ul style="list-style-type: none"><li>• Hydrogel—Amorphous;</li><li>• Hydrogel—Sheet</li></ul>	<ul style="list-style-type: none"><li>• Hydrogel—Amorphous;</li><li>• Hydrogel—Sheet</li></ul>

### Infected Wounds

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

### Malodorous Wounds

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

### Minor Skin Trauma

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

## Ordering Products

### Ordering Coloplast Products

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### Ordering Hartmann Products

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### Ordering Molnlycke Healthcare Products

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### Ordering Smith & Nephew Products

Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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## ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

*Antiinfectives and antiseptics for local oral treatment*

#### CHLORHEXIDINE

**chlorhexidine gluconate 0.2% mouthwash, 250 mL**

4161B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.30	7.70	Plaqacide [OB]

**chlorhexidine gluconate 0.2% mouthwash, 300 mL**

4204G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.16	7.70	Savacol Mouth and Throat Rinse [OM]

#### NYSTATIN

**nystatin 100 000 units/mL oral liquid, 24 mL**

10854G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	19.94	7.70	<sup>a</sup> Pharmacy Action Nystatin Oral Drops [GQ]	<sup>a</sup> Trust Nystatin Oral Drops [CR]
			..	21.18	7.70	<sup>a</sup> Mycostatin Oral Drops [LN]	

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

*Synthetic anticholinergics, esters with tertiary amino group*

#### MEBEVERINE

**mebeverine hydrochloride 135 mg tablet, 90**

4328T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	31.28	7.70	<sup>a</sup> APO-Mebeverine [TX]	<sup>a</sup> Colese [AF]
			..	35.78	7.70	<sup>a</sup> Colofac [GO]	

### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

#### HYOSCINE BUTYLBROMIDE

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

4279F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	20.52	7.70	<sup>a</sup> Buscopan [VZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE-AFT [AE]
						<sup>a</sup> HYOSCINE BUTYLBROMIDE MEDSURGE [DZ]	<sup>a</sup> HYOSCINE BUTYLBROMIDE SXP [XN]

## DRUGS FOR CONSTIPATION

### DRUGS FOR CONSTIPATION

*Softeners, emollients*

#### DOCUSATE

**docusate sodium 50 mg tablet, 100**

4200C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	20.32	7.70	Coloxyl 50 [AS]

*Contact laxatives*

#### BISACODYL

**bisacodyl 10 mg suppository, 10**

10578R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*26.10	7.70	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			..	*27.39	7.70	<sup>a</sup> Dulcolax [VZ]

## ALIMENTARY TRACT AND METABOLISM

### bisacodyl 10 mg suppository, 12

10580W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	4	..	*24.75	7.70	Petrus Bisacodyl Suppositories [PP]

### ▪ BISACODYL

#### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### bisacodyl 10 mg suppository, 10

14567Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*38.73	7.70	<sup>a</sup> Petrus Bisacodyl Suppositories [PP]
			..	*41.31	7.70	<sup>a</sup> Dulcolax [VZ]

### bisacodyl 10 mg suppository, 12

14572Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	4	..	*36.03	7.70	Petrus Bisacodyl Suppositories [PP]

### ▪ DOCUSATE + SENNOSIDE B

#### docosate sodium 50 mg + sennoside B 8 mg tablet, 90

10177P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	19.30	7.70	<sup>a</sup> Pharmacy Action Colox-Senna [HQ]	
			..	19.34	7.70	<sup>a</sup> Chemists' Own Laxative with Senna [RW]	<sup>a</sup> Colaxsen [AS]
						<sup>a</sup> Coloxyl with Senna [LN]	<sup>a</sup> Co-Senna [PP]
						<sup>a</sup> Trust Coloxease [CR]	

### ▪ SENNOSIDE B

#### sennoside B 7.5 mg tablet, 100

4455L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18.86	7.70	<sup>a</sup> Senna-Gen [PP]
			..	19.93	7.70	<sup>a</sup> Senokot [RC]

#### *Bulk-forming laxatives*

### ▪ DRY PSYLLIUM HUSK

#### dry psyllium husk 3.5 g powder for oral liquid, 30 sachets

4285M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	23.22	7.70	Fybogel [RC]

### ▪ PSYLLIUM HUSK POWDER

#### psyllium husk powder 3.4 g/5.9 g powder for oral liquid, 283 g

4419N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	26.72	7.70	Metamucil Orange Smooth [PY]

#### psyllium husk powder 3.4 g/7 g powder for oral liquid, 504 g

12596Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	33.24	7.70	Metamucil Natural Granular [PY]

#### *Enemas*

### ▪ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

#### sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL

4462W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.88	7.70	Micolette [AE]

#### *Other drugs for constipation*

### ▪ GLYCEROL

#### glycerol 1.4 g suppository, 12

10596Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*25.71	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

**glycerol 2.8 g suppository, 12**

4246L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*26.19	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

**glycerol 700 mg suppository, 12**

10586E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*25.35	7.70	Petrus Pharmaceuticals Pty Ltd [PP]

## ■ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### ANTIPROPULSIVES

#### *Antipropulsives*

## ■ LOPERAMIDE

**loperamide hydrochloride 2 mg capsule, 12**

10592L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.95	7.70	Gastrex [CR]

**loperamide hydrochloride 2 mg capsule, 20**

11135C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	15.26	7.70	<sup>a</sup> Gastrex [CR]	<sup>a</sup> Pharmacy Action Diarrhoea Relief [GQ]

## ■ ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

### ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

#### *Peripherally acting antiobesity products*

## ■ ORLISTAT

**Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

#### Authority required

Obesity

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

#### Authority required

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

#### Authority required

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

#### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

## ALIMENTARY TRACT AND METABOLISM

### orlistat 120 mg capsule, 84

4570M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	136.12	7.70	Xenical [PB]

## VITAMINS

### VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

#### Vitamin B1, plain

## THIAMINE

### thiamine hydrochloride 100 mg tablet, 100

4043T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	17.35	7.70	Betavit [PP]

## THIAMINE

#### Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### thiamine hydrochloride 100 mg tablet, 100

14182K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*21.25	7.70	Betavit [PP]

### VITAMIN B-COMPLEX, INCL. COMBINATIONS

#### Vitamin B-complex, plain

## LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE

lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL oral liquid, 200 mL

4493L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	19.48	7.70	Accomin Adult Tonic [PF]

## MINERAL SUPPLEMENTS

### CALCIUM

#### Calcium

## CALCIUM

#### Restricted benefit

Hyperphosphataemia

#### Clinical criteria:

- The condition must be associated with chronic renal failure.

### calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

4142B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*24.61	7.70	<sup>a</sup> Cal-care 600 mg [CR]
			..	*27.25	7.70	<sup>a</sup> CAL-600 [PP]

### calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

11845K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*29.55	7.70	Cal-500 [PP]

## CALCIUM

#### Restricted benefit

Hyperphosphataemia

#### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

### calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

14175C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	1	..	*35.75	7.70	<sup>a</sup> Cal-care 600 mg [CR]
			..	*41.03	7.70	<sup>a</sup> CAL-600 [PP]

### calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

14217G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	1	..	*45.63	7.70	Cal-500 [PP]

■ **CALCIUM****Restricted benefit**

Hypocalcaemia

**Restricted benefit**

Osteoporosis

**Restricted benefit**

Proven calcium malabsorption

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 120**

4082W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.03	7.70	<sup>a</sup> Cal-care 600 mg [CR]
			..	20.35	7.70	<sup>a</sup> CAL-600 [PP]

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

11862H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	21.50	7.70	Cal-500 [PP]

■ **CALCIUM****Restricted benefit**

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

Proven calcium malabsorption

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 120**

14174B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*24.61	7.70	<sup>a</sup> Cal-care 600 mg [CR]
			..	*27.25	7.70	<sup>a</sup> CAL-600 [PP]

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

14176D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*29.55	7.70	Cal-500 [PP]

**OTHER MINERAL SUPPLEMENTS***Magnesium*■ **MAGNESIUM****Restricted benefit**

Hypomagnesaemia

The condition must be documented in the patient's medical records.

**magnesium 37.4 mg tablet, 50**

4321K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	19.19	7.70	Mag-Sup [PP]	
			..	19.48	7.70	Amcal Mag-A [IG]	Pharmacy Care Magnesium [SI]
			..	20.05	7.70	Magmin [BB]	

■ **BLOOD AND BLOOD FORMING ORGANS**■ **ANTITHROMBOTIC AGENTS****ANTITHROMBOTIC AGENTS***Platelet aggregation inhibitors excl. heparin*■ **ASPIRIN****aspirin 100 mg tablet, 112**

10590J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	15.58	7.70	Spren 100 [OW]

## BLOOD AND BLOOD FORMING ORGANS

### aspirin 100 mg tablet, 90

4076M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	21.50	7.70	Cardiprin 100 [RC]

### ■ ASPIRIN

**Note** The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

### aspirin 100 mg enteric capsule, 84

4078P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	20.59	7.70	Astrix [YN]

### aspirin 100 mg enteric tablet, 84

4077N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	19.80	7.70	Cardasa [AF] <sup>a</sup> Cartia [AS] <sup>a</sup> Trust Aspirin EC 100 [CR]	<sup>a</sup> Pharmacy Action Low Dose Aspirin [GQ]

## ■ ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

*Iron bivalent, oral preparations*

### ■ FERROUS FUMARATE

#### ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60

10594N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.79	7.70	Ferro-tab [AE]

*Iron in combination with folic acid*

### ■ FERROUS FUMARATE + FOLIC ACID

#### ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

10579T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	20.76	7.70	Ferro-f-tab [AE]

### VITAMIN B12 AND FOLIC ACID

*Vitamin B12 (cyanocobalamin and analogues)*

### ■ HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B<sub>12</sub> deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

#### Restricted benefit

Pernicious anaemia

#### Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

#### Restricted benefit

Anaemias associated with vitamin B12 deficiency

#### **Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

#### hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10577Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	17.84	7.70	<sup>a</sup> Vita-B12 [GH]

#### hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10587F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	17.84	7.70	<sup>a</sup> Neo-B12 [PF]

*Folic acid and derivatives*

### ■ FOLIC ACID

#### folic acid 500 microgram tablet, 100

10584C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*17.67	7.70	<sup>a</sup> Foltabs 500 [PP]	<sup>a</sup> Megafol 0.5 [AF]



## ■ FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

### **follic acid 5 mg tablet, 100**

10573L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*19.75	7.70	Megafol 5 [AF]

## ■ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### IRRIGATING SOLUTIONS

*Salt solutions*

## ■ SODIUM CHLORIDE

### **sodium chloride 0.9% (9 g/L) solution, 1 L bottle**

4461T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.29	7.70	Baxter Healthcare Pty Ltd [BX]

### **sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle**

4460R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.03	7.70	Baxter Healthcare Pty Ltd [BX]

## ■ CARDIOVASCULAR SYSTEM

## ■ VASOPROTECTIVES

### AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

*Other agents for treatment of hemorrhoids and anal fissures for topical use*

## ■ ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

### **zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g**

4039N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	20.43	7.70	Anusol [JT]

### **zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12**

4040P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	19.49	7.70	Anusol [JT]

## ■ DERMATOLOGICALS

## ■ ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

*Imidazole and triazole derivatives*

## ■ CLOTRIMAZOLE

### **clotrimazole 1% cream, 20 g**

4004R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	15.51	7.70	<sup>a</sup> Pharmacy Action Anti-Fungal Cream [GQ]
			..	15.82	7.70	<sup>a</sup> Clonea [AF]

*Other antifungals for topical use*

## ■ AMOROLFINE

### Restricted benefit

Onychomycosis

### **amorolfine 5% solution, 5 mL**

4010C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	1	..	50.02	7.70	<sup>a</sup> Myconail [AE]	<sup>a</sup> Pharmacy Action Anti-Fungal Nail Treatment [GQ]
			..	86.27	7.70	<sup>a</sup> Aporyl [TX]	
			..	95.02	7.70	<sup>a</sup> Loceryl [AF]	

## ■ TERBINAFINE

### Restricted benefit

Tinea pedis

## DERMATOLOGICALS

### terbinafine 1% gel, 15 g

4463X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	28.18	7.70	Lamisil DermGel [NP]

### terbinafine hydrochloride 1% cream, 15 g

4473K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	1	..	26.91	7.70	<sup>a</sup> Lamisil [NP]	<sup>a</sup> Pharmacy Action Pharmisil [GQ]
						<sup>a</sup> Trust Terbinafine Cream [CR]	

## ■ TOLNAFTATE

### tolnaftate 0.07% spray, 100 g

4481W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	21.00	7.70	Tinaderm [BN]

## ANTIFUNGALS FOR SYSTEMIC USE

### *Antifungals for systemic use*

## ■ TERBINAFINE

### Authority required

Onychomycosis

### Clinical criteria:

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

### terbinafine 250 mg tablet, 42

4011D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	26.23	7.70	<sup>a</sup> APO-Terbinafine [TX]	<sup>a</sup> Tamsil [RW]
			..	33.48	7.70	<sup>a</sup> Terbinafine Sandoz [SZ]	<sup>a</sup> Tinasil [AF]
						<sup>a</sup> Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]	

## ■ EMOLLIENTS AND PROTECTIVES

### EMOLLIENTS AND PROTECTIVES

### *Soft paraffin and fat products*

## ■ WOOL ALCOHOLS

### wool alcohols 6% ointment, 100 g

4041Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	20.21	7.70	Eucerin [BE]

### *Carbamide products*

## ■ UREA

### urea 10% cream, 100 g

4042R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	18.54	7.70	Aquacare H.P. [VE]
			..	18.74	7.70	Urederm [KY]

### *Other emollients and protectives*

## ■ GELATIN + PECTIN + CARMELLOSE SODIUM

### gelatin 16.7% + pectin 16.7% + carmellose sodium 16.7% paste, 5 g

4518T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	18.26	7.70	Orabase [AS]

## ■ GLYCEROL + WHITE SOFT PARAFFIN

### glycerol 5% + white soft paraffin 5% lotion, 1 L

11712K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	32.66	7.70	QV Skin Lotion [EO]

## ■ SKIN EMOLLIENT

### SKIN EMOLLIENT Bath oil 500 mL, 1

4122Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	22.96	7.70	Alpha Keri Bath Oil [MT]
			..	25.06	7.70	QV Bath Oil [EO]
			..	25.14	7.70	Hamilton Skin Therapy Oil [KY]

### SKIN EMOLLIENT Lotion 500 mL, 1

4107E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	22.96	7.70	Alpha Keri Lotion [MT]

## PROTECTIVES AGAINST UV-RADIATION

*Protectives against UV-radiation for topical use*

## ■ BEMOTRIZINOL + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + HOMOSALATE + OCTOCRYLENE + TITANIUM DIOXIDE

**bemotrizinol 1.8% + diethylamino hydroxybenzoyl hexyl benzoate 4% + homosalate 8% + octocrylene 8% + titanium dioxide 2.5% lotion, 125 mL**

13188D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.57	7.70	Sunsense Comfort SPF 50+ [EO]

## ■ SUNSCREENS

### SUNSCREENS Cream 75 g, 1

4307Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.57	7.70	Sunsense Sensitive SPF 50+ [EO]

### SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

4546G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.77	7.70	Aquasun Lotion SPF 18 [PF]

## ■ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

**ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.**

*Anesthetics for topical use*

## ■ LIDOCAINE

### lidocaine hydrochloride 2% oral liquid, 200 mL

4308R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	105.58	7.70	Xylocaine Viscous [AS]

*Other antipruritics*

## ■ TAR + TROLAMINE LAURIL SULFATE

**Note** For patients who have failed to respond to simple moisturising agents.

### tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL

4408B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	27.81	7.70	Pinetarsol [EO]

## ■ ANTIPSORIATICS

**ANTIPSORIATICS FOR TOPICAL USE**

*Tars*

## ■ COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

### coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g

4505D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.81	7.70	Egopsoryl-TA [EO]

## ■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

**ANTIBIOTICS FOR TOPICAL USE**

*Other antibiotics for topical use*

## DERMATOLOGICALS

### ■ MUPIROCIN

#### mupirocin 2% ointment, 15 g

4350Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	22.08	7.70	<sup>a</sup> Medicianz Mupirocin Ointment [DZ]
			..	22.88	7.70	<sup>a</sup> APO-Mupirocin [TX]
			..	25.95	7.70	<sup>a</sup> Bactroban [GK]

### ■ MUPIROCIN

#### Restricted benefit

Secondarily infected traumatic skin lesions

#### mupirocin 2% cream, 15 g

4348W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	25.95	7.70	<sup>a</sup> Bactroban [GK]	<sup>a</sup> SUPIROCIN [JM]

## ■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

*Corticosteroids, weak (group I)*

### ■ HYDROCORTISONE ACETATE

#### hydrocortisone acetate 1% cream, 30 g

11710H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	18.68	7.70	<sup>a</sup> Pharmacy Action Hydrocortisone Cream 1% [GQ]	<sup>a</sup> Trust HydroCortic Cream [CR]

### ■ HYDROCORTISONE ACETATE

#### Restricted benefit

Corticosteroid-responsive dermatoses

#### hydrocortisone acetate 1% ointment, 30 g

10831C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	18.68	7.70	Cortic-DS 1% [AS]

*Corticosteroids, potent (group III)*

### ■ BETAMETHASONE VALERATE

#### betamethasone (as valerate) 0.1% cream, 30 g

4131K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	27.38	7.70	Betnovate [AS]

#### betamethasone (as valerate) 0.1% ointment, 30 g

4132L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	27.38	7.70	Betnovate [AS]

### ■ MOMETASONE

**Note** Application to large areas of skin for longer than four weeks is not recommended.

#### mometasone furoate 0.1% cream, 50 g

4342M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	36.99	7.70	Elocon Alcohol Free [AL]

#### mometasone furoate 0.1% ointment, 50 g

4343N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	36.99	7.70	Elocon [AL]

## ■ ANTISEPTICS AND DISINFECTANTS

### ANTISEPTICS AND DISINFECTANTS

*Iodine products*

### ■ POVIDONE-IODINE

#### povidone-iodine 10% solution, 100 mL

4411E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	27.10	7.70	Betadine Antiseptic Liquid [SW]

## OTHER DERMATOLOGICAL PREPARATIONS

### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

#### COAL TAR SOLUTION + SALICYLIC ACID

coal tar solution 4.25% + salicylic acid 2% shampoo, 200 mL

4560B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	25.60	7.70	Ionil-T [GA]

#### SELENIUM SULFIDE

selenium sulfide 2.5% shampoo, 125 mL

4452H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.17	7.70	Selsun [DQ]

#### TAR + COAL TAR SOLUTION + SALICYLIC ACID

tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL

4447C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	24.26	7.70	Sebitar [EO]

#### Wart and anti-corn preparations

#### SALICYLIC ACID + LACTIC ACID

salicylic acid 16.7% + lactic acid 15% solution, 15 mL

11959K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	23.66	7.70	Duofilm Solution [GK]

#### Other dermatologicals

#### DICLOFENAC

**Note** Maximum quantity of four tubes (original + 3 repeats) in 12 months.

##### Authority required

Solar (actinic) keratosis

Treatment Phase: Management

##### Clinical criteria:

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	63.02	7.70	Solaraze 3% Gel [YN]

#### GLYCEROL

glycerol 15% solution, 1 kg

11708F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	32.17	7.70	QV Gentle Wash [EO]

#### ICHTHAMMOL

**Note** For patients who have failed to respond to simple moisturising agents.

ichthammol 1% cream, 50 g

4281H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.62	7.70	Egoderma Cream [EO]

#### ICHTHAMMOL + ZINC OXIDE

**Note** For patients who have failed to respond to simple moisturising agents.

ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.62	7.70	Egoderma Ointment [EO]

#### IMIQUIMOD

##### Authority required

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

##### Clinical criteria:

## GENITO URINARY SYSTEM AND SEX HORMONES

- The condition must be confirmed by a histological diagnosis, **AND**
- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

### imiquimod 5% cream, 12 x 250 mg sachets

4559Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	88.99	7.70	<sup>a</sup> Aldiq [AF]	<sup>a</sup> APO-Imiquimod [TX]
			..	92.29	7.70	<sup>a</sup> Aldara [IL]	

### ■ IMIQUIMOD

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

#### Authority required

Solar keratosis

#### **Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

### imiquimod 5% cream, 2 x 2 g

10106X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	97.34	7.70	<sup>a</sup> Aldara Pump [IL]

### imiquimod 5% cream, 12 x 250 mg sachets

4134N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	88.99	7.70	<sup>a</sup> Aldiq [AF]	<sup>a</sup> APO-Imiquimod [TX]
			..	92.29	7.70	<sup>a</sup> Aldara [IL]	

### ■ LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

#### light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

4549K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	25.91	7.70	Hamilton Skin Therapy Wash [KY]

### ■ PANTHENOL

**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

#### panthenol conditioner, 200 g

4510J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	20.27	7.70	SebiRinse [EO]

### ■ ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN

#### zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% powder, 100 g

4497Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.59	7.70	Z.S.C. [RW]

## ■ GENITO URINARY SYSTEM AND SEX HORMONES

## ■ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

### ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

#### *Antibiotics*

### ■ NYSTATIN

#### nystatin 20 000 units/g vaginal cream, 75 g

4013F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	19.87	7.70	Nilstat [AS]

#### *Imidazole derivatives*

### ■ CLOTRIMAZOLE

#### clotrimazole 2% vaginal cream, 20 g

4017K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	..	..	20.99	7.70	<sup>a</sup> APO-Clotrimazole 3 Day Cream [TX]	<sup>a</sup> Clonea 3 Day Cream [AF]
						<sup>a</sup> Pharmacy Action FemCream 3 Day Cream [GQ]	<sup>a</sup> Trust Fem V 3 Day Cream [CR]

**clotrimazole 1% vaginal cream, 35 g**

4016J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	..	..	19.78	7.70	<sup>a</sup> Clonea 6 Day Cream [AF]	<sup>a</sup> Pharmacy Action FemCream [GQ]
			..	20.99	7.70	<sup>a</sup> Trust Fem V 6 Day Cream [CR] <sup>a</sup> APO-Clotrimazole 6 Day Cream [TX]	

## OTHER GYNECOLOGICALS

### OTHER GYNECOLOGICALS

#### ACETIC ACID + OXYQUINOLINE + RICINOLEIC ACID

**acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g**

4434J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	36.49	7.70	Aci-Jel [CU]

## UROLOGICALS

### UROLOGICALS

*Drugs used in erectile dysfunction*

#### ALPROSTADIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.
- Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**alprostadil 10 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes**

4579B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*120.66	7.70	Caverject Impulse [PF]

**alprostadil 20 microgram injection [1 chamber] (&) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes**

4580C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*152.97	7.70	Caverject Impulse [PF]

#### AVANAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**

- Patient must be male.
- Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**avanafil 100 mg tablet, 4**

11861G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	54.32	7.70	Spedra [FK]

**avanafil 200 mg tablet, 4**

11860F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.47	7.70	Spedra [FK]

**avanafil 50 mg tablet, 4**

11837B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.17	7.70	Spedra [FK]

## SILDENAFIL

### Authority required

Erectile dysfunction

### Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

### Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

### sildenafil 100 mg tablet, 4

4586J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.46	7.70	<sup>a</sup> Sildenafil Lupin [HQ]	<sup>a</sup> Viagra [UJ]
			..	73.98	7.70	<sup>a</sup> NOUMED Sildenafil [VO]	<sup>a</sup> Sildenafil APOTEX [GX]
						<sup>a</sup> Sildenafil Sandoz [SZ]	<sup>a</sup> Vasafil 100 [RW]
						<sup>a</sup> Vedafile [AF]	

### sildenafil 25 mg tablet, 4

4584G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	26.53	7.70	<sup>a</sup> Viagra [UJ]	
			..	57.41	7.70	<sup>a</sup> Sildenafil APOTEX [GX]	<sup>a</sup> Sildenafil Sandoz [SZ]
						<sup>a</sup> Vasafil 25 [RW]	<sup>a</sup> Vedafile [AF]

### sildenafil 50 mg tablet, 4

4585H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	30.10	7.70	<sup>a</sup> Sildenafil Lupin [HQ]	<sup>a</sup> Viagra [UJ]
			..	69.41	7.70	<sup>a</sup> NOUMED Sildenafil [VO]	<sup>a</sup> Sildenafil APOTEX [GX]
						<sup>a</sup> Sildenafil Sandoz [SZ]	<sup>a</sup> Vasafil 50 [RW]
						<sup>a</sup> Vedafile [AF]	

## TADALAFIL

### Authority required

Erectile dysfunction

### Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

### Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

### tadalafil 10 mg tablet, 4

4596X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	106.22	7.70	<sup>a</sup> Apo-Tadalafil [TX]	<sup>a</sup> Cialis [LY]
						<sup>a</sup> Cidala [RW]	<sup>a</sup> Cilatil [AF]
						<sup>a</sup> Cipla Tadalafil [LR]	<sup>a</sup> Tadalafil GH [GQ]
						<sup>a</sup> Tadalafil Sandoz [SZ]	

### tadalafil 20 mg tablet, 4

4597Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	106.22	7.70	<sup>a</sup> Apo-Tadalafil [TX]	<sup>a</sup> Cialis [LY]
						<sup>a</sup> Cidala [RW]	<sup>a</sup> Cilatil [AF]
						<sup>a</sup> Cipla Tadalafil [LR]	<sup>a</sup> Tadalacord [CR]
						<sup>a</sup> Tadalafil GH [GQ]	<sup>a</sup> Tadalafil Sandoz [SZ]

### Other urologicals

## BICARBONATE + CITRIC ACID + TARTARIC ACID

**Note** Pharmaceutical benefits that have the forms sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid and sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules are equivalent for the purposes of substitution.

### Restricted benefit

Urinary symptoms

### Clinical criteria:

- The treatment must be for when antibiotic or other therapy alone is inappropriate.



**sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules, 28 x 4 g sachets**

12179B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	19.66	7.70	<sup>a</sup> Trust Cystitis Relief [CR]

**sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets**

4049D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	4	..	19.66	7.70	<sup>a</sup> Pharmacy Action Cystitis Relief [GQ]	<sup>a</sup> Ural Sachets [AS]

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

### Alpha-adrenoreceptor antagonists

#### ■ ALFUZOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- Patient must have lower urinary tract symptoms.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

4277D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	77.03	7.70	Xatral SR [SW]

#### ■ ALFUZOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

14183L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*141.95	7.70	Xatral SR [SW]

#### ■ DUTASTERIDE + TAMSULOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- Patient must have lower urinary tract symptoms.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

10102Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	34.86	7.70	Duodart 500ug/400ug [GK]

#### ■ DUTASTERIDE + TAMSULOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

14184M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*56.27	7.70	Duodart 500ug/400ug [GK]

#### ■ SILODOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- Patient must have lower urinary tract symptoms.

**silodosin 4 mg capsule, 30**

12079R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	40.25	7.70	Urorec [YN]

## GENITO URINARY SYSTEM AND SEX HORMONES

### silodosin 8 mg capsule, 30

12077P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	45.00	7.70	Urorec [YN]

#### ■ SILODOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

### silodosin 4 mg capsule, 30

14185N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*67.05	7.70	Urorec [YN]

### silodosin 8 mg capsule, 30

14192Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*76.55	7.70	Urorec [YN]

#### ■ TAMSULOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- Patient must have lower urinary tract symptoms.

### tamsulosin hydrochloride 400 microgram modified release tablet, 30

4070F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	65.22	7.70	<sup>a</sup> Apo-Tamsulosin SR [TX]	<sup>a</sup> Blooms the Chemist Tamsulosin SR [IB]
						<sup>a</sup> BTC Tamsulosin SR [BG]	<sup>a</sup> Flomaxtra [LS]
						<sup>a</sup> Flosix [AF]	<sup>a</sup> Tamsulosin Lupin SR [GQ]
						<sup>a</sup> Tamsulosin Sandoz SR [SZ]	

#### ■ TAMSULOSIN

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

### tamsulosin hydrochloride 400 microgram modified release tablet, 30

14200J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*117.15	7.70	<sup>a</sup> Apo-Tamsulosin SR [TX]	<sup>a</sup> Blooms the Chemist Tamsulosin SR [IB]
						<sup>a</sup> BTC Tamsulosin SR [BG]	<sup>a</sup> Flomaxtra [LS]
						<sup>a</sup> Flosix [AF]	<sup>a</sup> Tamsulosin Lupin SR [GQ]
						<sup>a</sup> Tamsulosin Sandoz SR [SZ]	

### Testosterone-5-alpha reductase inhibitors

#### ■ DUTASTERIDE

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- Patient must have lower urinary tract symptoms.

### dutasteride 500 microgram capsule, 30

10095H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	29.82	7.70	<sup>a</sup> APO-Dutasteride [TX]
			..	36.82	7.70	<sup>a</sup> Avodart [GK]

#### ■ DUTASTERIDE

##### Authority required

Benign prostatic hyperplasia

##### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

**dutasteride 500 microgram capsule, 30**

14210X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*46.19	7.70	<sup>a</sup> APO-Dutasteride [TX]
			..	*60.19	7.70	<sup>a</sup> Avodart [GK]

▪ **FINASTERIDE**

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms.

**finasteride 5 mg tablet, 28**

4303L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	90.59	7.70	Finpro [RZ]

**finasteride 5 mg tablet, 30**

4233T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	78.25	7.70	<sup>a</sup> Finasteride GH 5 [GQ]	<sup>a</sup> Finasteride Mylan 5 [AF]
			..	96.10	7.70	<sup>a</sup> Finide [AL]	
			..	100.45	7.70	<sup>a</sup> Finnacar [RW]	
						<sup>a</sup> APO-Finasteride [TX]	<sup>a</sup> Finasta [SZ]
						<sup>a</sup> Finasteride-GA 5 [GN]	<sup>a</sup> Pharmacor Finasteride 5 [CR]
						<sup>a</sup> Proscar [OQ]	

▪ **FINASTERIDE**

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms.

**finasteride 5 mg tablet, 28**

14191X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*170.43	7.70	Finpro [RZ]

**finasteride 5 mg tablet, 30**

14199H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*144.51	7.70	<sup>a</sup> Finasteride GH 5 [GQ]	<sup>a</sup> Finasteride Mylan 5 [AF]
			..	*182.01	7.70	<sup>a</sup> Finide [AL]	
			..	*191.13	7.70	<sup>a</sup> Finnacar [RW]	
						<sup>a</sup> APO-Finasteride [TX]	<sup>a</sup> Finasta [SZ]
						<sup>a</sup> Finasteride-GA 5 [GN]	<sup>a</sup> Pharmacor Finasteride 5 [CR]
						<sup>a</sup> Proscar [OQ]	

▪ **ANTIINFECTIVES FOR SYSTEMIC USE**

▪ **ANTIBACTERIALS FOR SYSTEMIC USE**

**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**

*Macrolides*

▪ **AZITHROMYCIN**

**Restricted benefit**

Upper and lower respiratory tract infections

**azithromycin 500 mg tablet, 3**

4115N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	35.28	7.70	Zedd 500 [RW]	
						<sup>a</sup> APO-Azithromycin [TX]	<sup>a</sup> Azithromycin Mylan [AF]
						<sup>a</sup> Azithromycin Sandoz [SZ]	<sup>a</sup> Azithromycin Viatris [AL]
						<sup>a</sup> ZITHRO [RF]	<sup>a</sup> Zithromax [PF]

▪ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

▪ **ANTINEOPLASTIC AGENTS**

**ANTIMETABOLITES**

*Pyrimidine analogues*

## FLUOROURACIL

### fluorouracil 4% cream, 20 g

13758D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	68.30	7.70	TOLAK 4% ONCE DAILY [AS]

### fluorouracil 5% cream, 20 g

4222F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	..	..	67.65	7.70	<sup>a</sup> APOC-5FU [TX]	<sup>a</sup> Fluorouracil Viatris [AF]
			..	76.68	7.70	<sup>a</sup> Efudix [IL]	

## IMMUNOSUPPRESSANTS

### IMMUNOSUPPRESSANTS

*Tumor necrosis factor alpha (TNF-alpha) inhibitors*

## INFLIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab, or requests for forms, may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

#### Authority required

Rheumatoid arthritis

Treatment Phase: Initial treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

#### Population criteria:

- Patient must be an adult.

#### Clinical criteria:

- Patient must have active rheumatoid arthritis, **AND**
- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have a proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP) level, **AND**
- Patient must have proven erosive rheumatoid arthritis without end-stage disease, **AND**
- Patient must have failed an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or ciclosporin), unless these drugs were contraindicated or intolerance developed, **AND**
- Patient must have no history of active tuberculosis requiring treatment in the last 3 years, **AND**
- Patient must have no history of opportunistic infection in the last 2 months, **AND**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must be for the reduction of signs and symptoms and prevention of structural joint damage, **AND**
- Patient must not be pregnant or breastfeeding, **AND**
- Patient must be using an effective form of contraception if female and of child-bearing age.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

#### Authority required

Rheumatoid arthritis

Treatment Phase: Continuing treatment

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

#### Clinical criteria:

- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have previously been issued with an authority prescription for this drug for the treatment of this condition, **AND**
- Patient must have demonstrated an improvement in ESR and/or CRP level following the initial 3 dose course of therapy, **AND**
- Patient must have achieved an ACR20 (American College of Rheumatology) response by 14 weeks after the commencement of the initial course of therapy, **AND**
- The treatment must be in combination with methotrexate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

### infliximab 100 mg injection, 1 vial

4284L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	215.30	7.70	Remicade [JC]

## ■ MUSCULO-SKELETAL SYSTEM

## ■ TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

*Preparations with salicylic acid derivatives*

## ■ METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM EXTRACT

**methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum extract 0.15% cream, 100 g**

11707E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	20.07	7.70	Goanna Heat Cream [GQ]

## ■ DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

*Bisphosphonates*

## ■ RISEDRONATE

### Authority required

Preservation of bone mineral density

### Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
  - Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
  - Patient must be osteopenic (bone mineral density t-score of less than -1.0).
- Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### **risedronate sodium 35 mg tablet, 4**

4444X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.88	7.70	<sup>a</sup> APO-Risedronate [TX]	<sup>a</sup> Risedronate Sandoz [SZ]

### **risedronate sodium 35 mg enteric tablet, 4**

2191H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	33.88	7.70	Actonel EC [TT]

### **risedronate sodium 5 mg tablet, 28**

4443W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	37.47	7.70	Actonel [TT]

## ■ RISEDRONATE

### Authority required

Preservation of bone mineral density

### Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
  - Patient must be on long-term glucocorticoid therapy, **AND**
  - Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
  - Patient must be osteopenic (bone mineral density t-score of less than -1.0).
- Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### **risedronate sodium 35 mg tablet, 4**

14197F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*54.31	7.70	<sup>a</sup> APO-Risedronate [TX]	<sup>a</sup> Risedronate Sandoz [SZ]

### **risedronate sodium 35 mg enteric tablet, 4**

14198G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*54.31	7.70	Actonel EC [TT]

## NERVOUS SYSTEM

### risedronate sodium 5 mg tablet, 28

14209W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*61.49	7.70	Actonel [TT]

### *Bisphosphonates, combinations*

#### ■ ALENDRONATE + COLECALCIFEROL

##### Authority required

Preservation of bone mineral density

##### Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
  - Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
  - Patient must be osteopenic (bone mineral density t-score of less than -1.0).
- Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

2194L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	20.63	7.70	Fosamax Plus [MQ]

### alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

2224C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	20.63	7.70	Fosamax Plus 70 mg/140 mcg [MQ]

## ■ NERVOUS SYSTEM

## ■ ANALGESICS

### OPIOIDS

#### *Natural opium alkaloids*

#### ■ MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

##### Restricted benefit

Chronic severe disabling pain

##### Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

### morphine sulfate pentahydrate 200 mg modified release tablet, 28

4349X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	121.43	7.70	MS Contin [MF]

### *Opioids in combination with non-opioid analgesics*

#### ■ ASPIRIN + CODEINE

### aspirin 300 mg + codeine phosphate hemihydrate 8 mg dispersible tablet, 40

4286N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	20.21	7.70	Aspalgin 40 [GO]

#### ■ PARACETAMOL + CODEINE

### paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 40

4275B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.98	7.70	Panamax Co. 40 [SW]

### OTHER ANALGESICS AND ANTIPYRETICS

#### *Anilides*

#### ■ PARACETAMOL

### paracetamol 48 mg/mL oral liquid, 200 mL

10599W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	2	..	17.31	7.70	<sup>a</sup> Panamax 240 Elixir [SW]	<sup>a</sup> Trust for Kids Paracetamol 6 to 12 years [CR]

**paracetamol 500 mg tablet, 100**

10582Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	15.13	7.70	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

■ **PARACETAMOL****Restricted benefit**

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**paracetamol 665 mg modified release tablet, 96**

10598T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*20.99	7.70	<sup>a</sup> Osteomol 665 Paracetamol [CR] <sup>a</sup> Pharmacy Action OSTEO Relief 665 [HQ]	<sup>a</sup> Parapane OSTEO [XT] <sup>a</sup> Pharmacy Action Paracetamol Osteo 665 [GQ]

■ **PARACETAMOL****Restricted benefit**

Chronic arthropathies

**paracetamol 500 mg tablet, 100**

10585D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	4	..	*18.48	7.70	<sup>a</sup> APO-Paracetamol [TX] <sup>a</sup> Panamax [SW] <sup>a</sup> Paracetamol Sandoz Pharma [QS] <sup>a</sup> PHARMACY CARE PARACETAMOL [SI]	<sup>a</sup> Febridol [XT] <sup>a</sup> Paracetamol (Sandoz) [SZ] <sup>a</sup> Paralgin [OW] <sup>a</sup> Wagner Health Paracetamol [BG]

*Gabapentinoids*■ **GABAPENTIN****Authority required**

Refractory neuropathic pain

**Clinical criteria:**

- The condition must be unable to be controlled by other drugs.

**gabapentin 100 mg capsule, 100**

4591P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.63	7.70	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> Neurontin [UJ]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Nupentin 100 [AF]

**gabapentin 300 mg capsule, 100**

4592Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	23.10	7.70	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> Nupentin 300 [AF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Neurontin [UJ]

**gabapentin 400 mg capsule, 100**

4593R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	26.61	7.70	<sup>a</sup> APX-Gabapentin [GX] <sup>a</sup> Gabapentin Sandoz [SZ] <sup>a</sup> Nupentin 400 [AF]	<sup>a</sup> Gabacor [CR] <sup>a</sup> Neurontin [UJ]

**gabapentin 600 mg tablet, 100**

4594T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	34.06	7.70	<sup>a</sup> Gabapentin APOTEX [TY] <sup>a</sup> Pharmacor Gabapentin 600 [CR]	<sup>a</sup> Neurontin [UJ]

**gabapentin 800 mg tablet, 100**

4595W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	41.29	7.70	<sup>a</sup> Gabapentin APOTEX [TY] <sup>a</sup> Pharmacor Gabapentin 800 [CR]	<sup>a</sup> Neurontin [UJ]

## ■ PSYCHOLEPTICS

### ANXIOLYTICS

#### *Benzodiazepine derivatives*

## ■ BROMAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

#### Authority required

Terminal disease

#### **Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

#### Authority required

Refractory phobic or anxiety states

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **bromazepam 3 mg tablet, 30**

4150K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*33.53	7.70	Lexotan [PB]

#### **bromazepam 6 mg tablet, 30**

4151L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*39.27	7.70	Lexotan [PB]

## HYPNOTICS AND SEDATIVES

### *Benzodiazepine derivatives*

## ■ FLUNITRAZEPAM

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

#### Authority required

Terminal disease

#### **Clinical criteria:**

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

#### Authority required

Refractory phobic or anxiety states

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **flunitrazepam 1 mg tablet, 30**

4216X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	23.89	7.70	Hypnodorm [AF]

### *Benzodiazepine related drugs*

## ■ ZOPICLONE

#### Restricted benefit

Insomnia

#### **Clinical criteria:**

- The treatment must be for the short-term.

#### **zopiclone 7.5 mg tablet, 14**

13307J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	22.35	7.70	Imovane [SW]

#### **zopiclone 7.5 mg tablet, 30**

4522B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	26.80	7.70	<sup>a</sup> APO-Zopiclone [TX] <sup>a</sup> Imrest [AF] <sup>a</sup> Zopiclone GH [GQ] <sup>a</sup> Imovane [SW]	<sup>a</sup> Imclone [RW] <sup>a</sup> Pharmacor Zopiclone [CR]
			..	29.54	7.70		



## OTHER NERVOUS SYSTEM DRUGS

### DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in nicotine dependence*

#### NICOTINE

**Note** Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

##### Authority required

Nicotine dependence

##### Clinical criteria:

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

#### nicotine 14 mg/24 hours patch, 7

4572P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*57.11	7.70	QuitX [AF]

#### nicotine 21 mg/24 hours patch, 7

4573Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*60.07	7.70	QuitX [AF]

#### nicotine 7 mg/24 hours patch, 7

4571N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*53.95	7.70	QuitX [AF]

## ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

### ANTHELMINTICS

#### ANTINEMATODAL AGENTS

*Benzimidazole derivatives*

#### MEBENDAZOLE

**Note** Pharmaceutical benefits that have the forms mebendazole 100 mg tablet and mebendazole 100 mg chewable tablet are equivalent for the purposes of substitution.

#### mebendazole 100 mg tablet, 6

4325P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	19.66	7.70	<sup>a</sup> Pharmacy Action Worm Treatment [GQ]

#### mebendazole 100 mg chewable tablet, 6

12194T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	19.66	7.70	<sup>a</sup> Trust Deworm [CR]

## RESPIRATORY SYSTEM

### NASAL PREPARATIONS

#### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Sympathomimetics, plain*

#### OXYMETAZOLINE

#### oxymetazoline hydrochloride 0.05% nasal spray, 20 mL

11711J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	..	..	22.45	7.70	<sup>a</sup> Pharmacy Action Nasal Decongestant [GQ]	<sup>a</sup> Trust Decongestant Nasal Spray [CR]

#### oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

4378K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.79	7.70	Drixine [BN]

#### oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

4379L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.45	7.70	Logicin Rapid Relief [AS]

*Antiallergic agents, excl. corticosteroids*

## SENSORY ORGANS

### ■ CROMOGLYCATE

#### sodium cromoglycate 2% nasal spray, 26 mL

4468E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	27.80	7.70	Rynacrom [SW]

#### Corticosteroids

### ■ BUDESONIDE

#### Restricted benefit

Severe intractable rhinitis

#### budesonide 64 microgram/actuation nasal spray, 120 actuations

4092J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	44.05	7.70	Budamax Aqueous [JT]

## NASAL DECONGESTANTS FOR SYSTEMIC USE

### Sympathomimetics

### ■ PSEUDOEPHEDRINE

#### pseudoephedrine hydrochloride 60 mg tablet, 12

4029C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	16.99	7.70	<sup>a</sup> Pharmacy Action Sinus & Nasal Decongestant Relief [GQ]	<sup>a</sup> Trust Sinus & Nasal Decongestant [CR]

### ■ ANTIHISTAMINES FOR SYSTEMIC USE

## ANTI HISTAMINES FOR SYSTEMIC USE

### Piperazine derivatives

### ■ CETIRIZINE

#### cetirizine hydrochloride 10 mg tablet, 30

4175R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	30.43	7.70	<sup>a</sup> Pharmacy Action Cetrelief [GQ]	<sup>a</sup> Trust Cetirizine [CR]
			..	33.66	7.70	<sup>a</sup> Alzene [AF]	

#### Other antihistamines for systemic use

### ■ FEXOFENADINE

#### fexofenadine hydrochloride 120 mg tablet, 30

4238C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	30.25	7.70	<sup>a</sup> Pharmacy Action Fexorelief 120 [GQ]	<sup>a</sup> Trust Fexit 120 [CR]
			..	33.46	7.70	<sup>a</sup> Xergic [AF]	
			..	49.67	7.70	<sup>a</sup> Telfast 120 [SW]	

#### fexofenadine hydrochloride 60 mg tablet, 20

4237B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*57.54	7.70	Telfast [SW]

### ■ LORATADINE

#### loratadine 10 mg tablet, 30

4313B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	32.86	7.70	<sup>a</sup> Pharmacy Action Lorastyne [GQ]	<sup>a</sup> Trust Loratadine [CR]
						<sup>a</sup> Trust Loratadine Antihistamine [RM]	
			..	36.56	7.70	<sup>a</sup> Allereze [AF]	
			..	48.46	7.70	<sup>a</sup> Claratyne [BN]	

### ■ SENSORY ORGANS

### ■ OPHTHALMOLOGICALS

## ANTIINFECTIVES

### Antibiotics

## ■ CHLORAMPHENICOL

### chloramphenicol 0.5% eye drops, 10 mL

14180H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.57	7.70	Chlorsig [AS]

## ■ OTOLOGICALS

### OTHER OTOLOGICALS

*Indifferent preparations*

## ■ CARBAMIDE PEROXIDE

### carbamide peroxide 6.5% ear drops, 12 mL

4176T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.94	7.70	Ear Clear for Ear Wax Removal [KY]

## ■ DOCUSATE

### docusate sodium 0.5% ear drops, 10 mL

4199B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.46	7.70	Waxsol [GO]

## ■ ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL

### ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% ear drops, 10 mL

4180B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.12	7.70	Cerumol [UN]

## ■ VARIOUS

## ■ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

*Drugs for treatment of hyperkalemia and hyperphosphatemia*

## ■ SODIUM POLYSTYRENE SULFONATE

### sodium polystyrene sulfonate 999.3 mg/g powder, 454 g

4470G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	83.15	7.70	Resonium-A [SW]

## ■ GENERAL NUTRIENTS

### OTHER NUTRIENTS

*Other combinations of nutrients*

## ■ PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

### Restricted benefit

Stage 2 and above pressure injury

### Clinical criteria:

- The treatment must be for special medical purposes to support healing of pressure injuries.

### protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 200 mL bottles

11401C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*207.33	7.70	Cubitan [SB]

## ■ ALL OTHER NON-THERAPEUTIC PRODUCTS

### ALL OTHER NON-THERAPEUTIC PRODUCTS

## ■ LUBRICATING AGENT

### lubricating agent gel, 100 g

4306P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	16.87	7.70	Lubri-Gel [PP]

*Other non-therapeutic auxiliary products*

## ■ BANDAGE ABSORBENT WOOL

### bandage absorbent wool 10 cm x 3 m bandage, 1

4653X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	25.55	7.70	Surepress 650948 [CC]

## ■ BANDAGE CALICO

### bandage calico large triangular bandage, 1

4717G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.47	7.70	Handy 36361414 [BV]

## ■ BANDAGE COMPRESSION

### bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack

11714M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	40.05	7.70	Rosidal TCS 26484 [LC]

## ■ BANDAGE COMPRESSION

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### bandage compression two layer bandage, 1

12592R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	53.15	7.70	Putter Pro 2 931685 [HR]

## ■ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

### bandage compression 10 cm x 3 m high stretch bandage, 1

4748X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*73.92	7.70	Surepress 650947 [CC]
			..	*154.17	7.70	Tensopress 71723-00 [BV]

### bandage compression 8 cm x 2.6 m short stretch bandage, 1

4654Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*79.27	7.70	Comprilan 01027-00 [BV]

## ■ BANDAGE COMPRESSION

**Note** Use with caution if arterial disease present and avoid if severe arterial disease.

**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

### bandage compression 25 cm to 32 cm two layer bandage, 1

13010R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	48.46	7.70	UrgoK2 100397 [UG]

### bandage compression 25 cm to 32 cm two layer bandage, 1

13016C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	48.46	7.70	UrgoK2 Lite 100401 [UG]

### bandage compression 18 cm to 25 cm two layer bandage, 1

13005L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	42.64	7.70	UrgoK2 100396 [UG]

### bandage compression 18 cm to 25 cm two layer bandage, 1

13006M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	42.64	7.70	UrgoK2 Lite 100400 [UG]

## ■ BANDAGE COMPRESSION

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage compression four layer bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4598B	5	..	..	*215.57	7.70	Profore Lite 66050415 [SN]

**bandage compression four layer bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4658E	5	..	..	*322.02	7.70	Profore 66050016 [SN]

**▪ BANDAGE COMPRESSION**

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

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**bandage compression 10 cm x 3.5 m high stretch bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4657D	5	..	..	*79.07	7.70	Setopress 3505 [MH]

**▪ BANDAGE COMPRESSION**

**Note** Use with caution if arterial disease present and avoid if severe arterial disease.

**Note** Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**Restricted benefit**

Venous ulcer

Treatment Phase: Initial treatment

**Restricted benefit**

Venous ulcer

Treatment Phase: Continuing treatment

**bandage compression two layer bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4050E	1	..	..	45.22	7.70	Coban 2 [MM]

**▪ BANDAGE RETENTION COHESIVE HEAVY****bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4813H	2	..	..	*26.21	7.70	Peg 7423 [MM]

**bandage retention cohesive heavy 10 cm x 2 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4660G	2	..	..	*24.73	7.70	Coban 1584 [MM]

**bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4814J	2	..	..	*32.39	7.70	Peg 7425 [MM]

**bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4811F	2	..	..	*20.07	7.70	Peg 7420 [MM]

**bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4812G	2	..	..	*22.93	7.70	Peg 7422 [MM]

**▪ BANDAGE RETENTION COHESIVE LIGHT****bandage retention cohesive light 10 cm x 2 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4662J	2	..	..	*35.85	7.70	Handygauze Cohesive 8635 [BV]

**bandage retention cohesive light 6 cm x 2 m bandage, 1**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4719J	2	..	..	*21.99	7.70	Handygauze Cohesive 8633 [BV]

**bandage retention cohesive light 2.5 cm x 2 m bandage, 2**

4718H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.60	7.70	Handygauze Cohesive 8631 [BV]

**▪ BANDAGE RETENTION COTTON CREPE****bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

4728W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.21	7.70	Telfa 8253F [KE]
			..	*30.25	7.70	Tensocrepe 36307501 [BV]

**bandage retention cotton crepe 10 cm x 2.3 m bandage, 1**

4729X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.95	7.70	Telfa 8254F [KE]
			..	*35.39	7.70	Tensocrepe 36301001 [BV]

**bandage retention cotton crepe 5 cm x 2.3 m bandage, 1**

4727T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*23.03	7.70	Telfa 8252F [KE]
			..	*25.69	7.70	Tensocrepe 36300501 [BV]

**▪ BANDAGE TUBULAR****bandage tubular size C (15 cm to 25 cm) straight bandage, 1**

4663K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.26	7.70	Elastoplast 2225 [BE]

**bandage tubular size D (25 cm to 43 cm) straight bandage, 1**

4664L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.26	7.70	Elastoplast 2226 [BE]

**bandage tubular size E (35 cm to 45 cm) straight bandage, 1**

4665M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.26	7.70	Elastoplast 2227 [BE]

**▪ BANDAGE TUBULAR**

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**bandage tubular 10 cm x 1 m bandage, 1**

4859R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.90	7.70	Tubigrip F 1548 [MH]

**bandage tubular 6.25 cm x 1 m bandage, 1**

4855M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.90	7.70	Tubigrip B 1520 [MH]

**bandage tubular 6.75 cm x 1 m bandage, 1**

4856N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.90	7.70	Tubigrip C 1545 [MH]

**bandage tubular 7.5 cm x 1 m bandage, 1**

4857P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.90	7.70	Tubigrip D 1546 [MH]

**bandage tubular 8.75 cm x 1 m bandage, 1**

4858Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.90	7.70	Tubigrip E 1547 [MH]

**▪ BANDAGE TUBULAR FINGER****BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1**

4798M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	23.33	7.70	Tubegauz 0501633 [SS]

**▪ BANDAGE TUBULAR LIGHT WEIGHT**

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(IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com.  
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#### bandage tubular light weight 10 m large limb size bandage, 1

4673Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	32.34	7.70	Tubifast 2438 [MH]

#### bandage tubular light weight 10 m medium limb size bandage, 1

4672X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	31.11	7.70	Tubifast 2436 [MH]

#### bandage tubular light weight 10 m small limb size bandage, 1

4671W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	27.67	7.70	Tubifast 2434 [MH]

### ▪ BANDAGE TUBULAR LONG STOCKING

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#### bandage tubular long stocking large size bandage, 1

4799N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*40.17	7.70	Tubigrip 1484 [MH]

#### bandage tubular long stocking medium size bandage, 1

4797L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*40.17	7.70	Tubigrip 1483 [MH]

#### bandage tubular long stocking small size bandage, 1

4674B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*40.17	7.70	Tubigrip 1482 [MH]

#### bandage tubular long stocking XX/large size bandage, 1

4675C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*40.19	7.70	Tubigrip 1486 [MH]

### ▪ BANDAGE TUBULAR SHORT STOCKING

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com.  
Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

#### bandage tubular short stocking large D/E size bandage, 1

4816L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.95	7.70	Tubigrip 1481 [MH]

#### bandage tubular short stocking medium C/D size bandage, 1

4815K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.95	7.70	Tubigrip 1480 [MH]

#### bandage tubular short stocking small B/C size bandage, 1

4661H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.95	7.70	Tubigrip 1479 [MH]

### ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

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Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

#### bandage zinc paste 7.5 cm x 6 m bandage, 1

4669R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*33.67	7.70	Steripaste 3610 [MH]

### ▪ BANDAGE ZINC PASTE

**Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

## VARIOUS

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

### bandage zinc paste 7.5 cm x 6 m bandage, 1

4750B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*101.89	7.70	Viscopaste 4948 [SN]

### bandage zinc paste 80 cm (stockings) bandage, 4

4760M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	116.89	7.70	ZipZoc 66000747 [SN]

## ▪ BETAINE + POLYAMINOPROPYL BIGUANIDE

### betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules

2525X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	31.07	7.70	Prontosan Wound Irrigation Solution [BR]

## ▪ CADEXOMER-IODINE

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet

4936T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	209.57	7.70	Iodosorb 66051340 [SN]

### cadexomer-iodine 3 g powder, 7 sachets

4931M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	95.68	7.70	Iodosorb Powder 66051070 [SN]

### cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet

4937W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	220.86	7.70	Iodosorb 66051360 [SN]

### cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet

4935R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	144.73	7.70	Iodosorb 66051330 [SN]

### cadexomer-iodine 50% ointment, 4 x 10 g

4932N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	153.21	7.70	Iodosorb Ointment 66051240 [SN]

### cadexomer-iodine 50% ointment, 2 x 20 g

4933P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	151.74	7.70	Iodosorb Ointment 66051230 [SN]

## ▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

### dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

4681J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*99.37	7.70	Actisorb Plus MAP105 [KI]

### dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10

4742N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	79.42	7.70	CarboFLEX 403202 [CC]

### dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

4743P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	89.32	7.70	CarboFLEX 403204 [CC]

## ▪ DRESSING ALGINATE CAVITY WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.



**dressings alginate cavity wound 2 g rope, 1**

4832H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*106.87	7.70	Sorbsan 1411 [UM]

**dressings alginate cavity wound 2 g rope, 5 x 2 g**

1905G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*112.41	7.70	Kaltostat 168117 [CC]

**■ DRESSING ALGINATE CAVITY WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressings alginate cavity wound 2 g (40 cm) rope, 6 x 2 g**

4682K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*133.79	7.70	Comfeel SeaSorb Filler 3740 [CT]

**■ DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**dressings alginate superficial wound 7.5 cm x 12 cm dressing, 10**

4683L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	90.42	7.70	Kaltostat 168212 [CC]

**■ DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings alginate superficial wound 10 cm x 10 cm dressing, 10**

4700J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	137.65	7.70	Algisite M 66000520 [SN]

**dressings alginate superficial wound 15 cm x 20 cm dressing, 10**

4691X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	335.39	7.70	Algisite M 66000521 [SN]

**dressings alginate superficial wound 5 cm x 5 cm dressing, 10**

4699H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	51.94	7.70	Kaltostat 168210 [CC]
			..	72.83	7.70	Algisite M 66000519 [SN]

**■ DRESSING ALGINATE SUPERFICIAL WOUND**

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressings alginate superficial wound 10 cm x 10 cm dressing, 1**

4831G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*84.37	7.70	Sorbsan 1410 [UM]
			..	*89.57	7.70	Comfeel SeaSorb Dressing 3710 [CT]

**dressings alginate superficial wound 5 cm x 5 cm dressing, 1**

4684M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*49.47	7.70	Comfeel SeaSorb Dressing 3705 [CT]

## ■ DRESSING ALGINATE WITH MANUKA HONEY

**Note** Suitable for yellow sloughy infected and malodorous wounds.

### dressings alginate with manuka honey 10 cm x 10 cm dressing, 5

10849B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	71.52	7.70	Algivon Plus CR4225 [DJ]

### dressings alginate with manuka honey 2.5 cm x 20 cm ribbon, 5

10857K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	83.22	7.70	Algivon Plus Ribbon & Probe CR4231 [DJ]

## ■ DRESSING ALGINATE WITH SILVER CAVITY WOUND

### Authority required

Wounds

### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressings alginate with silver cavity wound 3 cm x 44 cm dressing, 10

12765W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	401.56	7.70	Melgisorb Ag 256605 [MH]

## ■ DRESSING ALGINATE WITH SILVER DEEP WOUND

### Authority required

Wounds

### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressings alginate with silver deep wound 5 cm x 5 cm dressing, 10

12772F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	136.82	7.70	Melgisorb Ag 256055 [MH]

### dressings alginate with silver deep wound 10 cm x 10 cm dressing, 10

12801R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	237.41	7.70	Melgisorb Ag 256105 [MH]

## ■ DRESSING CONTACT LAYER LIPIDOCOLLOID

### dressings contact layer lipidocolloid 10 cm x 10 cm dressing, 10

13022J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	71.61	7.70	UrgoTul Contact 100351 [UG]

## ■ DRESSING CONTACT LAYER LIPIDOCOLLOID WITH SUCROSE OCTASULFATE

### dressings contact layer lipidocolloid with sucrose octasulfate 15 cm x 20 cm dressing, 10

13011T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	229.55	7.70	UrgoStart Contact-Interface-Tul 100381 [UG]

### dressings contact layer lipidocolloid with sucrose octasulfate 10 cm x 10 cm dressing, 10

13002H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	125.87	7.70	UrgoStart Contact-Interface-Tul 100380 [UG]

## ■ DRESSING FILM

### dressings film 15 cm x 20 cm dressing, 1

4688R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*34.53	7.70	Tegaderm Transparent 1628 [MM]

### dressings film 10 cm x 12 cm dressing, 4

4687Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	24.96	7.70	Nexcare Tegaderm Transparent H1626 [MM]

### dressings film 6 cm x 7 cm dressing, 8

4686P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.48	7.70	Nexcare Tegaderm Transparent H1624 [MM]

## ■ DRESSING FILM

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressings film 10 cm x 12 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4893M	±1	..	..	47.37	7.70	Op-Site Flexigrid 4629 [SN]

## ■ DRESSING FILM ISLAND

### dressings film island 5 cm x 7 cm dressing, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4689T	10	..	..	*21.97	7.70	Tegaderm Transparent Island 3582 [MM]

### dressings film island 9 cm x 10 cm dressing, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4690W	10	..	..	*31.97	7.70	Tegaderm Transparent Island 3586 [MM]

## ■ DRESSING FILM ISLAND

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### dressings film island 5 cm x 7.2 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4898T	2	..	..	*37.43	7.70	Cutifilm Plus 36361370 [SN]

### dressings film island 8 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4899W	2	..	..	*55.85	7.70	Cutifilm Plus 36361371 [SN]

## ■ DRESSING FOAM HEAVY EXUDATE

### Restricted benefit

Wounds

### Clinical criteria:

- Patient must have a wound with highly viscous exudate.

### dressings foam heavy exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12760N	±1	..	..	44.26	7.70	Mepilex XT 211100 [MH]

### dressings foam heavy exudate 20 cm x 20 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12776K	±1	..	..	131.86	7.70	Mepilex XT 211400 [MH]

### dressings foam heavy exudate 5 cm x 5 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12797M	±1	..	..	38.24	7.70	Mepilex XT 211015 [MH]

## ■ DRESSING FOAM HEAVY EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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### dressings foam heavy exudate 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4795J	±1	1	..	178.83	7.70	Allevyn 66007637 [SN]

## ■ DRESSING FOAM LIPIDOCOLLOID WITH SILICONE HEAVY EXUDATE

### dressing foam lipidocolloid with silicone heavy exudate 10 cm x 10 cm dressing, 10

13007N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	94.94	7.70	UrgoTul Absorb Silicone Border 102203 [UG]

## ■ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE

### dressing foam lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10

13023K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	128.96	7.70	UrgoStart Border 100480 [UG]

### dressing foam lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10

13017D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	166.53	7.70	UrgoStart Border 100481 [UG]

### dressing foam lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10

13021H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	363.63	7.70	UrgoStart Border 100482 [UG]

## ■ DRESSING FOAM LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

### dressing foam lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10

13008P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	139.08	7.70	UrgoStart Pad 100376 [UG]

### dressing foam lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10

13003J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	301.99	7.70	UrgoStart Pad 100377 [UG]

### dressing foam lipidocolloid with sucrose octasulfate moderate exudate 12 cm x 19 cm dressing, 10

13004K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	226.19	7.70	UrgoStart Pad 100378 [UG]

## ■ DRESSING FOAM MODERATE EXUDATE

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### dressing foam moderate exudate cavity conforming foam, 20 g sachet

4694C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	101.29	7.70	Cavicare 4563 [SN]

## ■ DRESSING FOAM MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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### dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

4590N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	177.54	7.70	Allevyn Adhesive 66000044 [SN]

## ■ DRESSING FOAM WITH SILICONE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing foam with silicone 10.5 cm x 10.5 cm dressing, 10

11384E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	69.51	7.70	Allevyn Life Non-Bordered 66801748 [SN]

**dressing foam with silicone 16 cm x 16 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11393P	‡1	..	..	118.38	7.70	Allevyn Life Non-Bordered 66801749 [SN]

**dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10017F	‡1	..	..	74.61	7.70	Allevyn Life 66801067 [SN]

**dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10029W	‡1	..	..	105.22	7.70	Allevyn Life 66801068 [SN]

**dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10023M	‡1	..	..	145.77	7.70	Allevyn Life 66801069 [SN]

**dressing foam with silicone 21 cm x 21 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10021K	‡1	..	..	293.58	7.70	Allevyn Life 66801070 [SN]

**▪ DRESSING FOAM WITH SILICONE AND SILVER**

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2439J	‡1	..	..	106.99	7.70	Mepilex Ag [MH]

**dressing foam with silicone and silver 10 cm x 10 cm dressing, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2470B	‡1	..	..	114.07	7.70	Mepilex Border Ag [MH]

**▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE****dressing foam with silicone heavy exudate 15 cm x 20 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12185H	‡1	..	..	179.39	7.70	Mepilex Border Flex 595611 [MH]

**dressing foam with silicone heavy exudate 22 cm x 23 cm dressing, 6**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12195W	‡1	..	..	168.99	7.70	Mepilex Border Heel 282750 [MH]

**dressing foam with silicone heavy exudate 16 cm x 20 cm dressing, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12216Y	‡1	..	..	85.55	7.70	Mepilex Border Sacrum 282050 [MH]

**dressing foam with silicone heavy exudate 22 cm x 25 cm dressing, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12207L	‡1	..	..	129.26	7.70	Mepilex Border Sacrum 282450 [MH]

**dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12206K	‡1	..	..	72.49	7.70	Mepilex Border Flex 595311 [MH]

**dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12184G	‡1	..	..	54.43	7.70	Mepilex Border Flex 595211 [MH]

## ■ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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### ■ dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4196W	±1	..	..	87.60	7.70	Allevyn Gentle 66800248 [SN]

### ■ dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4230P	±1	..	..	96.64	7.70	Allevyn Gentle Border 66800270 [SN]

### ■ dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4207K	±1	..	..	68.93	7.70	Allevyn Gentle Border 66800269 [SN]

## ■ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

### ■ dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12804X	±1	..	..	40.45	7.70	Mepilex Border Lite 281300 [MH]

### ■ dressing foam with silicone light exudate 4 cm x 5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12780P	±1	..	..	30.88	7.70	Mepilex Border Lite 281000 [MH]

### ■ dressing foam with silicone light exudate 5 cm x 12.5 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12774H	±1	..	..	33.46	7.70	Mepilex Border Lite 281100 [MH]

## ■ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### ■ dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4645L	±1	..	..	41.10	7.70	Mepilex Lite 284100 [MH]

### ■ dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4644K	±1	..	..	32.28	7.70	Mepilex Lite 284000 [MH]

## ■ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

### ■ dressing foam with silicone moderate exudate 5 cm x 12.5 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12782R	±1	..	..	31.74	7.70	Mepilex Border Flex Lite 581100 [MH]

### ■ dressing foam with silicone moderate exudate 4 cm x 5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12777L	±1	..	..	29.05	7.70	Mepilex Border Flex Lite 581011 [MH]

### ■ dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12799P	±1	..	..	38.35	7.70	Mepilex Border Flex Lite 581300 [MH]

## ■ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

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**dressings foam with silicone moderate exudate 10 cm x 10 cm dressing, 5**

4626L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	45.22	7.70	Mepilex 294100 [MH]

**■ DRESSING FOAM WITH SILVER**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressings foam with silver 7.5 cm x 7.5 cm dressing, 10**

4252T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	182.70	7.70	Allevyn Ag Adhesive 66800073 [SN]

**dressings foam with silver 7.5 cm x 7.5 cm dressing, 10**

4263J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	182.70	7.70	Allevyn Ag Gentle Border 66800460 [SN]

**dressings foam with silver 10 cm x 10 cm dressing, 10**

4255Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	271.76	7.70	Allevyn Ag Adhesive 66800075 [SN]

**dressings foam with silver 10 cm x 10 cm dressing, 10**

4259E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	276.98	7.70	Allevyn Ag Non-Adhesive 66800086 [SN]

**dressings foam with silver 10 cm x 10 cm dressing, 10**

4266M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	271.76	7.70	Allevyn Ag Gentle Border 66800461 [SN]

**dressings foam with silver 12.5 cm x 12.5 cm dressing, 10**

4258D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	337.59	7.70	Allevyn Ag Adhesive 66800078 [SN]

**dressings foam with silver 12.5 cm x 12.5 cm dressing, 10**

4270R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	337.59	7.70	Allevyn Ag Gentle Border 66800462 [SN]

**■ DRESSING GAUZE****dressings gauze eye pad, 12 pads**

4768Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.05	7.70	Curity 4112 [KE]

**■ DRESSING GAUZE ABSORBENT****dressings gauze absorbent 10 cm x 10 cm pad, 100**

4708T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.79	7.70	Handy 71117-06 [BV]

**dressings gauze absorbent 5 cm x 5 cm pad, 100**

4707R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.06	7.70	Handy 71117-05 [BV]

**■ DRESSING GAUZE PARAFFIN**

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**dressing gauze paraffin 10 cm x 10 cm dressing, 10**

4759L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	31.29	7.70	Jelonet 7404 [SN]

**▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10**

4845B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	40.05	7.70	Bactigras 7457 [SN]

**▪ DRESSING GELLING FIBRE****dressing gelling fibre 10 cm x 10 cm dressing, 10**

12181D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	76.57	7.70	Exufiber 709901 [MH]

**dressing gelling fibre 5 cm x 5 cm dressing, 10**

12187K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	42.17	7.70	Exufiber 709900 [MH]

**dressing gelling fibre 15 cm x 15 cm dressing, 10**

12202F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	159.85	7.70	Exufiber 709903 [MH]

**dressing gelling fibre 1 cm x 45 cm dressing, 5**

12213T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	53.46	7.70	Exufiber 709908 [MH]

**dressing gelling fibre 2 cm x 45 cm dressing, 5**

12182E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	53.46	7.70	Exufiber 709909 [MH]

**▪ DRESSING GELLING FIBRE**

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**dressing gelling fibre 10 cm x 10 cm dressing, 10**

2486W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	128.57	7.70	Durafiber 66800560 [SN]

**dressing gelling fibre 15 cm x 15 cm dressing, 5**

2445Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*267.83	7.70	Durafiber 66800561 [SN]

**dressing gelling fibre 2 cm x 45 cm rope, 5**

2462N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	109.84	7.70	Durafiber 66800563 [SN]

**▪ DRESSING GELLING FIBRE LIPIDOCOLLOID****dressing gelling fibre lipidocolloid 15 cm x 20 cm dressing, 10**

13009Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	234.25	7.70	UrgoClean Pad 100372 [UG]

**dressing gelling fibre lipidocolloid 10 cm x 10 cm dressing, 10**

13015B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	106.46	7.70	UrgoClean Pad 100370 [UG]

**▪ DRESSING HYDROACTIVE DEBRIDEMENT**

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.



**dressing hydroactive debridement 4 cm dressing, 10**

12636C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	93.38	7.70	HydroClean Plus Cavity 609622 [HR]

**dressing hydroactive debridement 4 cm dressing, 10**

12637D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	89.55	7.70	HydroClean Plus 609602 [HR]

**dressing hydroactive debridement 4 cm dressing, 10**

4949L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	84.79	7.70	TenderWet 24 Active 609210 [HR]

**dressing hydroactive debridement 5.5 cm dressing, 10**

12629Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	148.59	7.70	HydroClean Plus 609606 [HR]

**dressing hydroactive debridement 5.5 cm dressing, 10**

4948K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	86.65	7.70	TenderWet Active Cavity 609272 [HR]

**dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10**

12660H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	197.64	7.70	HydroClean Plus 609608 [HR]

**dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10**

4950M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	112.39	7.70	TenderWet 24 Active 609213 [HR]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM****dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings**

4695D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	108.75	7.70	Tielle MTL101E [KI]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings**

4696E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	131.99	7.70	Tielle MTL103 [KI]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM**

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10**

4929K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	95.76	7.70	Biatain Adhesive 3420 [CT]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5**

4930L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	92.91	7.70	Biatain Adhesive 3423 [CT]

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10**

4927H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	87.56	7.70	Biatain Non-adhesive 3410 [CT]

**dressings hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5**

4928J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	86.21	7.70	Biatain Non-adhesive 3413 [CT]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10**

4905E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	84.68	7.70	Allevyn Thin 66047576 [SN]

**dressings hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5**

4906F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*152.91	7.70	Allevyn Thin 66047578 [SN]

**▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

4886E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*100.49	7.70	Cutinova Hydro 66047443 [SN]

**dressings hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10**

4885D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	61.94	7.70	Cutinova Hydro 66047441 [SN]

**▪ DRESSING HYDROCOLLOID CAVITY WOUND**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressings hydrocolloid cavity wound paste, 30 g**

4896Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*140.87	7.70	DuoDERM Paste 187930 [CC]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**dressings hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4907G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	72.82	7.70	DuoDERM Extra Thin 187955 [CC]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressings hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4924E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	71.06	7.70	Comfeel Plus Transparent 3533 [CT]

**dressings hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10**

4888G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	44.26	7.70	Comfeel Plus Transparent 3530 [CT]

**dressings hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10**

4889H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	84.46	7.70	Comfeel Plus Transparent 3536 [CT]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressings hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10**

4947J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	50.69	7.70	Hydrocoll Thin 900758 [HR]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**dressings hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5**

4920Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*216.25	7.70	DuoDERM CGF 187662 [CC]

**dressings hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5**

4897R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*81.63	7.70	DuoDERM CGF 187660 [CC]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

4921B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	110.32	7.70	Replicare Ultra 66000434 [SN]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressings hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10**

4946H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	89.36	7.70	Hydrocoll 900936 [HR]

**dressings hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10**

4945G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	50.69	7.70	Hydrocoll 900744 [HR]

**▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1**

4923D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	82.17	7.70	Comfeel Plus Ulcer Dressing 3110 [CT]

**dressings hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1**

4679G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*61.82	7.70	Comfeel Plus Pressure Relieving 3353 [CT]

**dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1**

4678F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*57.72	7.70	Comfeel Plus Pressure Relieving 3350 [CT]

**▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES****dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

10837J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	123.03	7.70	Aquacel Foam Non-Adhesive [CC]

**dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10**

2797F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	99.42	7.70	Aquacel Extra 420672 [CC]

**dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5**

2803M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*201.95	7.70	Aquacel Extra 420673 [CC]

**dressing hydrofibre alternate to alginates 2 cm x 45 cm ribbon, 5**

4698G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	83.72	7.70	Aquacel 403770 [CC]

**dressing hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10**

10832D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	119.38	7.70	Aquacel Foam Adhesive [CC]

**▪ DRESSING HYDROFIBRE WITH SILVER****Authority required**

Wounds

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing hydrofibre with silver 10 cm x 10 cm dressing, 10**

10097K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	257.98	7.70	Aquacel Ag 403708 [CC]

**dressing hydrofibre with silver 15 cm x 15 cm dressing, 5**

10098L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	275.88	7.70	Aquacel Ag 403710 [CC]

**dressing hydrofibre with silver 2 cm x 45 cm ribbon, 5**

10105W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	218.48	7.70	Aquacel Ag 403771 [CC]

**▪ DRESSING HYDROGEL****dressing hydrogel 10 cm x 10 cm dressing, 5**

11709G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	32.01	7.70	Suprasorb G 33631 [LC]

**dressing hydrogel 7.5 cm x 15 cm dressing, 10**

11395R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	115.71	7.70	Sorbact Gel Dressing S98137 [BV]

**dressing hydrogel 10 cm x 10 cm dressing, 20**

2471C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	186.83	7.70	Sorbact Absorption Dressing S98222 [BV]

**▪ DRESSING HYDROGEL**

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressings hydrogel 12.5 cm x 12.5 cm dressing, 5**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12659G	‡1	..	..	43.67	7.70	Hydrosorb Comfort 900723 [HR]

**■ DRESSING HYDROGEL AMORPHOUS**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**dressings hydrogel amorphous gel, 50 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4914P	3	3	..	*36.69	7.70	Solugel 10336 [JJ]

**dressings hydrogel amorphous gel, 3 x 30 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4913N	3	1	..	*95.91	7.70	DuoDERM Gel H7987 [CC]

**■ DRESSING HYDROGEL AMORPHOUS**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**dressings hydrogel amorphous gel, 10 x 15 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4912M	‡1	1	..	66.24	7.70	DuoDERM Gel 187990 [CC]
			..	73.16	7.70	Comfeel Purilon Gel 3900 [CT]

**■ DRESSING HYDROGEL AMORPHOUS**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**dressings hydrogel amorphous gel, 25 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4894N	4	3	..	*90.35	7.70	Intrasite Gel 7313 [SN]

**dressings hydrogel amorphous gel, 50 g**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4599C	3	3	..	*43.47	7.70	SoloSite Gel 36361338 [SN]

**■ DRESSING HYDROGEL FOAM****dressings hydrogel foam 10 cm x 10 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2533H	1	..	..	127.01	7.70	Sorbact Foam Dressing S98310 [BV]

**■ DRESSING HYDROGEL RIBBON****dressings hydrogel ribbon 1 cm x 50 cm dressing, 20**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2512F	1	..	..	189.09	7.70	Sorbact Ribbon Gauze S98118 [BV]

**dressings hydrogel ribbon 5 cm x 200 cm dressing, 10**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2529D	1	..	..	186.83	7.70	Sorbact Ribbon Gauze S98120 [BV]

**■ DRESSING HYDROGEL SHEET**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5**

4911L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*83.27	7.70	Nu-Gel 2497 [KI]

**■ DRESSING HYDROGEL SHEET**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing hydrogel sheet 10 cm x 10 cm dressing, 5**

4806Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*55.83	7.70	Hydrosorb 900854 [HR]

**■ DRESSING HYDROPHOBIC****dressing hydrophobic 15 cm x 15 cm foam dressing, 10**

11404F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	206.03	7.70	Sorbact Foam Dressing S98315 [BV]

**dressing hydrophobic 10 cm x 10 cm dressing, 10**

11392N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	200.38	7.70	Sorbact Foam Gentle Border 98532 [BV]

**dressing hydrophobic 10 cm x 10 cm dressing, 10**

11402D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	91.41	7.70	Sorbact Superabsorbent 98501 [BV]

**dressing hydrophobic 15 cm x 15 cm dressing, 10**

11394Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	313.28	7.70	Sorbact Foam Gentle Border 98533 [BV]

**dressing hydrophobic 20 cm x 20 cm dressing, 10**

11403E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	245.54	7.70	Sorbact Superabsorbent 98503 [BV]

**■ DRESSING LIPIDOCOLLOID MODERATE EXUDATE****dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 10**

13331P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	80.72	7.70	UrgoTul Lite Border 10035710 [UG]

**dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 16**

13026N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	121.47	7.70	UrgoTul Lite Border 100357 [UG]

**■ DRESSING NON ADHERENT**

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1**

4243H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	65.46	7.70	Mepitel 290510 [MH]

**DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1**

4244J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	105.46	7.70	Mepitel 290710 [MH]

## ■ DRESSING NON ADHERENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### ■ dressing non adherent 7.5 cm x 10 cm dressing, 10

4944F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.13	7.70	Atrauman 499513 [HR]

## ■ DRESSING NON ADHERENT

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### ■ dressing non adherent 10 cm x 10 cm dressing, 10

4861W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	46.29	7.70	Melolin 66974933 [SN]

### ■ dressing non adherent 10 cm x 10 cm dressing, 5

4862X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*33.53	7.70	Cutilin Non-Stick Wound Pad 36361375 [SN]

### ■ dressing non adherent 5 cm x 5 cm dressing, 5

4819P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*23.37	7.70	Cutilin Non-Stick Wound Pad 36361374 [SN]

### ■ dressing non adherent 5 cm x 5 cm dressing, 5

4860T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*25.09	7.70	Melolin 36361357 [SN]

## ■ DRESSING NON-ADHERENT ABSORBENT

### ■ dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

11717Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	27.65	7.70	Vliwasorb Pro 32641 [LC]

### ■ dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

12837P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.21	7.70	Mextra Superabsorbent 610000 [MH]

### ■ dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10

11715N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	38.51	7.70	Vliwasorb Pro 32643 [LC]

### ■ dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10

11718R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	51.09	7.70	Vliwasorb Pro 32644 [LC]

### ■ dressing non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10

12834L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	53.24	7.70	Mextra Superabsorbent 610300 [MH]

### ■ dressing non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10

12833K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	90.87	7.70	Mextra Superabsorbent 610500 [MH]

### ■ dressing non-adherent absorbent 10 cm x 13 cm dressing, 50

12832J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	58.08	7.70	Mesorb 677001 [MH]

### ■ dressing non-adherent absorbent 10 cm x 23 cm dressing, 50

12825B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	78.51	7.70	Mesorb 677401 [MH]

**dressing non-adherent absorbent 23 cm x 25 cm dressing, 30**

12824Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	101.52	7.70	Mesorb 677701 [MH]

**▪ DRESSING NON-ADHERENT ABSORBENT**

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing non-adherent absorbent 10 cm x 10 cm hydroactive dressing, 10**

12600E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	39.32	7.70	Zetuvit Plus 413710 [HR]

**dressing non-adherent absorbent 10 cm x 20 cm hydroactive dressing, 10**

12593T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	45.78	7.70	Zetuvit Plus 413711 [HR]

**dressing non-adherent absorbent 20 cm x 40 cm hydroactive dressing, 10**

12599D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	97.50	7.70	Zetuvit Plus 413715 [HR]

**▪ DRESSING NON-ADHERENT WITH SILICONE****dressing non-adherent with silicone 10 cm x 18 cm dressing, 10**

12196X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	310.11	7.70	Mepitel One 289500 [MH]

**dressing non-adherent with silicone 5 cm x 7.5 cm dressing, 10**

12208M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	93.13	7.70	Mepitel One 289100 [MH]

**▪ DRESSING NON-ADHERENT WITH SILICONE**

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing non-adherent with silicone 7.5 cm x 10 cm dressing, 5**

12651W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	66.23	7.70	Atrauman Silicone 499561 [HR]

**▪ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE HEAVY EXUDATE****dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 8 cm x 8 cm dressing, 10**

13013X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	205.13	7.70	UrgoStart Plus Border 100460 [UG]

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10**

13014Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	266.62	7.70	UrgoStart Plus Non Adhesive 100441 [UG]

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 10 cm x 10 cm dressing, 10**

13019F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	280.13	7.70	UrgoStart Plus Border 100461 [UG]

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 10**

13024L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	637.49	7.70	UrgoStart Plus Border 100462 [UG]

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate heavy exudate 15 cm x 20 cm dressing, 5**

13018E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	307.27	7.70	UrgoStart Plus Non Adhesive 100442 [UG]



## ■ DRESSING POLY-ABSORBENT FIBRE LIPIDOCOLLOID WITH SUCROSE OCTASULFATE MODERATE EXUDATE

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 10 cm x 10 cm dressing, 10**

13025M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	210.11	7.70	UrgoStart Plus Pad 100421 [UG]

**dressing poly-absorbent fibre lipidocolloid with sucrose octasulfate moderate exudate 15 cm x 20 cm dressing, 10**

13012W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	475.32	7.70	UrgoStart Plus Pad 100422 [UG]

## ■ DRESSING TULLE NON-ADHERENT PRIMARY WOUND CONTACT LAYER PARAFFIN

**dressing tulle non-adherent primary wound contact layer paraffin 7.6 cm x 7.6 cm dressing, 1**

4909J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*21.57	7.70	Adaptic 2012 [KI]

## ■ DRESSING WITH SILVER

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### Authority required

Wounds

### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 10 cm x 10 cm tulle dressing, 10**

12591Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	117.06	7.70	Atrauman Ag 499573 [HR]

**dressing with silver 10 cm x 10 cm tulle dressing, 3**

4648P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	46.32	7.70	Atrauman Ag 499572 [HR]

## ■ DRESSING WITH SILVER

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### Authority required

Wounds

### Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5**

4647N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	184.92	7.70	Biatain Ag 9632 [CT]

**dressing with silver 10 cm x 10 cm hydroactive dressing, 5**

4646M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	170.21	7.70	Biatain Ag 9622 [CT]

## ■ GAUZE AND COTTON TISSUE COMBINE ROLL

**gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1**

4761N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.84	7.70	JJ 12010 [JJ]

**gauze and cotton tissue combine roll 9 cm x 10 m wrapped pack roll, 1**

4767X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	18.23	7.70	BSN 2902165 [BV]

## ■ PAD WOUND DEBRIDEMENT

**Note** If the wound has not healed during this period, further use is to be discontinued after initial pack, no repeats. Where wounds remain unresponsive to standard treatment, patient should be referred on to a specialist.

### pad wound debridement 10 cm x 10 cm pad, 5

11383D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	93.83	7.70	Debrisoft [LC]

### pad wound debridement pad, 5

11391M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	93.83	7.70	Debrisoft Lolly [LC]

## ■ POVIDONE-IODINE

### povidone-iodine 9.5 cm x 9.5 cm dressing, 25

10847X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	80.01	7.70	Inadine [KI]

## ■ SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

### sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL

11134B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	32.81	7.70	Microdacyn [TF]

## ■ TAPE NON WOVEN RETENTION POLYACRYLATE

### tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

4915Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	19.09	7.70	Medipore 2961 [MM]

## ■ TAPE NON WOVEN RETENTION POLYACRYLATE

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

4917T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	17.61	7.70	Mefix 310250 [MH]

## ■ TAPE PLASTER ADHESIVE ELASTIC

### tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	19.99	7.70	Leukoplast 01071-00 [BV]

### tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	25.93	7.70	Leukoplast 01072-00 [BV]

### tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	29.61	7.70	Leukoplast 01073-00 [BV]

## ■ TAPE PLASTER ADHESIVE HYPOALLERGENIC

### tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll

4848E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	17.62	7.70	Nexcare Durable Cloth First Aid Tape 799 [MM]

### tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll

4849F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	17.62	7.70	Nexcare Gentle Paper First Aid Tape 789 [MM]

### tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4783R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	17.53	7.70	Leukopor 2471 [BV]

**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

4785W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	17.80	7.70	Leukosilk 1021 [BV]

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4787Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.34	7.70	Leukosilk 1022 [BV]

**tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll**

4794H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	19.81	7.70	Leukopor 2472 [BV]

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4788B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.84	7.70	Leukoflex 1124 [BV]

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4789C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	24.16	7.70	Leukosilk 1024 [BV]

**tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll**

4790D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	23.33	7.70	Leukopor 2474 [BV]

**■ TAPE PLASTER ADHESIVE WITH SILICONE**

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**tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll**

4239D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	26.46	7.70	Mepitac 298300 [MH]

**tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll**

4240E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	26.46	7.70	Mepitac 298400 [MH]

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# Extemporaneously Prepared Benefits

# Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia, powdered	BP	0.04	0.36	3.24	20.59
Acetic Acid (33 per cent)	BP	0.02	0.18	1.76	17.58
Acetic Acid (6 per cent)	BP	0.01	0.04	0.41	4.11
Acetone (use as additive only)	BP	0.04	0.41	3.72	33.06
Alum	BP	0.07	0.70	6.28	55.79
Aluminium Acetate Solution	BP	0.02	0.22	2.02	17.98
Anise Water Concentrated 1 in 40	BP	0.01	0.08	0.81	8.09
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.52	4.63
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.14	1.39	12.47	79.16
Aspirin	BP	0.39	3.95	35.54	315.90
Belladonna Tincture	BP	0.34	3.36	30.28	269.16
Benzocaine	BP	0.29	2.87	16.39	163.90
Benzoic Acid	BP	0.22	2.23	20.03	127.16
Benzoic Acid Compound Ointment	APF	0.02	0.24	2.19	19.47
Benzoic Acid Solution	BP	0.03	0.25	2.51	25.06
Benzoin Compound Tincture	BP	0.05	0.52	4.65	41.30
Boric Acid (use as additive only)	BP	0.07	0.67	6.03	38.27
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.22	2.02	12.84
Calcium Hydroxide	BP	0.28	2.77	24.94	158.34
Calcium Hydroxide Solution	BP	0.01	0.04	0.39	3.88
Castor Oil (use as additive only)	BP	0.01	0.15	1.31	11.60
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.07	0.64	5.70
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.13	1.17	10.42
Chlorhexidine Acetate (use as additive only)	BP	0.77	7.74	44.20	442.03
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.50	4.48
Chloroform (use as additive only)	BP	0.11	1.11	10.01	88.97
Chloroform Spirit	BP	0.01	0.10	0.99	9.89
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.13	1.31	13.08
Citric Acid Monohydrate	BP	0.11	1.06	9.57	60.79
Coal Tar	BP	0.06	0.55	4.99	44.33
Coal Tar Solution	BP	0.03	0.29	2.61	16.60
Cocaine Hydrochloride	BP	158.19	1581.90	9039.45	90394.50
Coconut Oil	BP	0.06	0.58	5.18	32.92
Codeine Linctus	APF	0.02	0.19	1.67	10.58
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	8.74	87.43	499.59	4995.90
Collodion Flexible	BP	0.54	5.37	48.34	306.92
Dithranol	BP	4.17	41.73	238.48	2384.76
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.13	1.16	10.34
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	3.03	30.27	272.41	1729.56
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.06	0.51	4.56
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.07	0.66	5.91
Ether Solvent (use as additive only)	BP	0.29	2.35	18.83	167.36
Eucalyptus Oil (use as additive only)	BP	0.02	0.22	1.94	17.27

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Ferrous Sulfate	BP	0.09	0.94	8.47	53.76
Formaldehyde Solution	BP	0.05	0.54	4.85	43.14
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.01	0.12	1.10	9.79
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.09	0.68	5.42	48.17
Iodine	BP	1.46	14.60	83.46	834.57
Iodine Alcoholic Solution	BP	0.05	0.50	4.51	28.65
Iodine Aqueous Oral Solution	BP	0.05	0.45	4.06	25.80
Kaolin Mixture	BPC 1968	0.04	0.39	3.47	30.80
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.35	3.51	31.63	200.83
Lavender Spike Oil	BPC 1968	0.13	1.29	11.57	73.44
Liquorice Liquid Extract	BP	0.19	1.85	16.69	148.40
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.10	0.94	8.33
Magnesium Trisilicate	BP	0.06	0.61	5.53	49.14
Menthol, Racemic or Levomenthol	BP	0.29	2.94	26.49	168.16
Methyl Hydroxybenzoate	BP	0.52	5.17	46.49	295.16
Methyl Hydroxybenzoate Solution	APF	0.05	0.53	5.31	53.13
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.11	0.95
Olive Oil (use as additive only)	BP	0.01	0.10	0.94	8.34
Paraffin Hard	BP	0.07	0.75	6.73	59.83
Paraffin Light Liquid	BP	0.01	0.14	1.28	8.13
Paraffin Liquid (use as additive only)	BP	0.01	0.10	0.94	8.39
Paraffin Soft White	BP	0.01	0.08	0.74	6.53
Peppermint Oil (use as additive only)	BP	0.10	1.02	9.14	58.00
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.05	0.46	4.10	36.48
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	1.47	14.69	132.17	839.16
Phenol Liquefied (not available for ear drops)	BP	0.46	4.60	41.39	262.77
Podophyllum Resin	BP	9.07	90.74	518.49	5184.90
Potassium Citrate	BP	0.03	0.34	3.10	27.58
Potassium Iodide	BP	0.58	5.78	52.06	330.54
Potassium Permanganate	BP	0.07	0.67	6.07	53.95
Propyl Hydroxybenzoate	BP	0.46	4.61	41.45	263.16
Propylene Glycol	BP	0.03	0.32	2.87	18.25
Resorcinol	BP	0.45	3.57	28.59	254.15
Salicylic Acid	BP	0.06	0.59	5.33	33.82
Salicylic Acid Ointment	APF	0.02	0.17	1.38	12.23
Salicylic Acid Ointment	BP	0.02	0.17	1.38	12.23
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.20	1.82	16.15
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.04	0.36	3.23	28.74
Sodium Chloride	BP	0.03	0.30	2.69	23.88
Sodium Chloride Solution	BP	0.01	0.01	0.14	1.38
Sodium Citrate	BP	0.06	0.57	5.13	32.54
Sodium Thiosulfate (use as additive only)	BP	0.09	0.92	8.30	73.76
Starch	BP	0.02	0.23	2.03	18.05
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.17	1.72	17.21
Sulfur Precipitated	BP 1980	0.03	0.30	2.68	17.00
Syrup	BP	0.01	0.07	0.60	5.30
Talc Purified, sterilised	BP	6.35	63.49	571.39	5079.04
Thymol	BP	0.59	5.94	53.42	339.16
Thymol Compound Mouth Wash	APF 15	0.01	0.11	0.95	8.42
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.11	1.13	11.27
Tragacanth Mucilage	BPC 1973	0.01	0.11	1.06	10.55
Tragacanth, powdered	BP	0.74	7.38	66.45	421.89
Trichloroacetic Acid	BP 1980	0.33	3.26	29.33	186.24

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Triethanolamine	BP	0.18	1.78	15.98	101.46
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0.00	0.00	11.42	11.42
Water Purified	BP	0.01	0.01	0.13	1.12
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.03	0.21	1.64	14.55
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.05	0.48	4.31	38.35
Wool Fat Hydrous	BP	0.03	0.30	2.68	23.78
Zinc Compound Paste	BP	0.05	0.48	4.36	38.78
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.02	0.22	2.02	17.94
Zinc Oxide	BP	0.05	0.53	4.78	42.47
Zinc Sulfate	BP	0.09	0.87	7.84	49.78
Zinc and Salicylic Acid Paste	BP	0.04	0.37	3.36	29.86

# Container Prices

Type	Container	Price \$
Dispensing Bottles	25mL	1.74
Dispensing Bottles	50mL	0.73
Dispensing Bottles	100mL	0.87
Dispensing Bottles	200mL	0.96
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	1.21
Poison Bottles	50mL	1.30
Poison Bottles	100mL	1.36
Poison Bottles	200mL	1.48
Poison Bottles	500mL	2.00
Poison Bottles	600mL	4.05
Poison Bottles	1000mL	3.99
Dropper Containers (Glass)	15mL	1.67
Dropper Containers (Polythene)	15mL	0.98
Screw Cap Jars	25g	0.65
Screw Cap Jars	50g	1.36
Screw Cap Jars	100g	1.38
Screw Cap Jars	200g	0.77
Screw Cap Jars	500g	2.19
Screw Cap Jars	1000g	4.39



# Standard Formula Preparations

Code	Item	Reference	DPMQ \$	MRVSN \$
	<b>Creams</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7502W	Salicylic Acid and Sulfur Aqueous	APF	18.31	20.18
	<b>Ear Drops</b>			
	<b>(Maximum Quantity 15 ml and 2 Repeats)</b>			
7643G	Aluminium Acetate	BP	14.72	16.59
7642F	Aluminium Acetate	APF	13.59	15.46
7314Y	Sodium Bicarbonate	APF & BP	12.63	14.50
7313X	Spirit	APF	12.17	14.04
	<b>Inhalations</b>			
	<b>(Maximum Quantity 50 ml and 1 Repeat)</b>			
7484X	Benzoin and Menthol	APF	37.72	31.60
7308P	Menthol	APF	17.47	19.34
7310R	Menthol and Eucalyptus	BP1980	18.23	20.10
	<b>Linctuses containing Codeine Phosphate</b>			
	<b>(Maximum Quantity 100 ml and 0 Repeat)</b>			
7530H	Codeine	APF	22.16	24.03
	<b>Lotions</b>			
	<b>(Maximum Quantity 200 ml and 2 Repeats)</b>			
7709R	Aluminium Acetate Aqueous	APF	16.34	18.21
	<b>Mixtures, Other</b>			
	<b>(Maximum Quantity 200 ml and 4 Repeats)</b>			
7348R	Kaolin	BPC 1968	55.67	31.60
7342K	Magnesium Trisilicate	BPC 1968	28.93	30.80
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	45.58	31.60
	<b>Ointments, Waxes</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7914M	Benzoic Acid Compound	APF & BP	31.56	31.60
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	24.93	26.80
7926E	Salicylic Acid	APF	25.12	26.99
7928G	Salicylic Acid (extemporaneous formula)	BP	25.12	26.99
	<b>Paints</b>			
	<b>(Maximum Quantity 25 ml and 1 Repeat)</b>			
7567G	Podophyllin Compound	APF 16 & BP	362.05	31.60
7568H	Salicylic Acid	APF	122.16	31.60
	<b>Pastes, Other</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7558T	Zinc	APF & BP	50.87	31.60
	<b>Powders for Internal Use</b>			
	<b>(Maximum Quantity 100 g and 2 Repeats)</b>			
7545D	Magnesium Trisilicate	BP	60.62	31.60

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

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# Index of Manufacturers Codes

<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>AB</b>	Abbott Australasia Pty Ltd	<b>IB</b>	Apotex Pty Ltd
<b>AE</b>	AFT Pharmaceuticals (AU) Pty Ltd	<b>IE</b>	BeiGene AUS Pty Ltd
<b>AF</b>	Alphapharm Pty Ltd	<b>IG</b>	Sigma Company Limited
<b>AL</b>	Alphapharm Pty Ltd	<b>IL</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>AN</b>	Amgen Australia Pty Limited	<b>IM</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>AP</b>	AstraZeneca Pty Ltd	<b>IO</b>	BioMarin Pharmaceutical Australia Pty Ltd
<b>AQ</b>	Alcon Laboratories (Australia) Pty Ltd	<b>IQ</b>	Alcon Laboratories (Australia) Pty Ltd
<b>AS</b>	Aspen Pharmacare Australia Pty Limited	<b>IR</b>	Indivior Pty Ltd
<b>AV</b>	sanofi-aventis Australia Pty Ltd	<b>IS</b>	Ipsen Pty Ltd
<b>BB</b>	Blackmores Limited	<b>IT</b>	InterPharma Pty Ltd
<b>BD</b>	Biogen Australia Pty Ltd	<b>IU</b>	AUPHARMA PTY LTD
<b>BE</b>	Beiersdorf Australia Ltd	<b>IX</b>	Clinect Pty Ltd
<b>BG</b>	Sandoz Pty Ltd	<b>IY</b>	Clinect Pty Ltd
<b>BN</b>	Bayer Australia Ltd	<b>JA</b>	JAZZ PHARMACEUTICALS ANZ PTY LTD
<b>BQ</b>	Bristol-Myers Squibb Australia Pty Ltd	<b>JC</b>	Janssen-Cilag Pty Ltd
<b>BR</b>	B. Braun Australia Pty Ltd	<b>JJ</b>	Johnson & Johnson Medical Pty Ltd
<b>BV</b>	BSN medical (Aust.) Pty Ltd	<b>JM</b>	Glenmark Pharmaceuticals (Australia) Pty Ltd
<b>BX</b>	BAXTER HEALTHCARE PTY LTD	<b>JO</b>	Juno Pharmaceuticals Pty Ltd
<b>BY</b>	Boehringer Ingelheim Pty Ltd	<b>JT</b>	Johnson & Johnson Pacific Pty Limited
<b>BZ</b>	Boucher & Muir Pty Ltd	<b>JU</b>	Juno Pharmaceuticals Pty Ltd
<b>CC</b>	ConvaTec Australia Pty Ltd	<b>JX</b>	Juno Pharmaceuticals Pty Ltd
<b>CF</b>	CNS Pharma Pty Ltd	<b>JZ</b>	Juniper Biologics Pty Ltd
<b>CR</b>	Pharmacor Pty Limited	<b>KE</b>	Kendall Australasia Pty Ltd
<b>CS</b>	Seqirus (Australia) Pty Ltd	<b>KI</b>	KCI Medical Australia Pty Ltd
<b>CT</b>	Coloplast Pty Ltd	<b>KO</b>	KYOWA KIRIN AUSTRALIA PTY LTD
<b>CU</b>	Care Pharmaceuticals Pty Limited	<b>KP</b>	Eli Lilly Australia Pty Ltd
<b>CX</b>	Contact Lens Centre Australia Limited	<b>KQ</b>	PHERO PHARMA PTY LTD
<b>DE</b>	Stallergenes Australia Pty Ltd	<b>KY</b>	Key Pharmaceuticals Pty Ltd
<b>DJ</b>	De Fries Industries Pty Ltd	<b>LC</b>	Lohmann & Rauscher Pty Ltd
<b>DQ</b>	Church & Dwight (Australia) Pty Ltd	<b>LG</b>	Leo Pharma Pty Ltd
<b>DV</b>	Medical Developments International Limited	<b>LL</b>	Astellas Pharma Australia Pty Ltd
<b>DX</b>	Ascensia Diabetes Care Australia Pty Limited	<b>LM</b>	Link Medical Products Pty Ltd
<b>DZ</b>	Medsurge Healthcare Pty Ltd	<b>LN</b>	Aspen Pharmacare Australia Pty Limited
<b>EI</b>	Eisai Australia Pty Ltd	<b>LO</b>	Leo Pharma Pty Ltd
<b>EJ</b>	Encapsulate Pharma Pty Ltd	<b>LQ</b>	Astellas Pharma Australia Pty Ltd
<b>EO</b>	Ego Pharmaceuticals Pty Ltd	<b>LR</b>	Cipla Australia Pty Ltd
<b>EU</b>	Chiesi Australia Pty Ltd	<b>LS</b>	Astellas Pharma Australia Pty Ltd
<b>EV</b>	Teva Pharma Australia Pty Ltd	<b>LT</b>	Aspen Pharmacare Australia Pty Limited
<b>EW</b>	Celltrion Healthcare Australia Pty Ltd	<b>LU</b>	Lundbeck Australia Pty Ltd
<b>FB</b>	Pierre Fabre Australia Pty Ltd	<b>LX</b>	Lawley Pharmaceuticals Pty Ltd
<b>FD</b>	Dr Falk Pharma Australia Pty Ltd	<b>LY</b>	Eli Lilly Australia Pty Ltd
<b>FF</b>	Phebra Pty Ltd	<b>MF</b>	Mundipharma Pty Limited
<b>FG</b>	Phebra Pty Ltd	<b>MH</b>	Molnlycke Health Care Pty Ltd
<b>FI</b>	Boehringer Ingelheim Pty Ltd	<b>MK</b>	Merck Sharp & Dohme (Australia) Pty Ltd
<b>FJ</b>	Pharmaco (Australia) Limited	<b>MM</b>	3M Pharmaceuticals Australia Pty Ltd
<b>FK</b>	A.Menarini Australia Pty Limited	<b>MQ</b>	Alphapharm Pty Ltd
<b>FP</b>	Ferring Pharmaceuticals Pty Limited	<b>MT</b>	Mentholatum Australasia Pty Ltd
<b>FQ</b>	Pharmaco (Australia) Limited	<b>MW</b>	Biomed Aust Pty Limited
<b>FT</b>	AMICUS THERAPEUTICS PTY LTD	<b>NB</b>	Nova Pharmaceuticals Australasia Pty Ltd
<b>FX</b>	Gedeon Richter Australia Pty Ltd	<b>NE</b>	Norgine Pty. Ltd.
<b>FZ</b>	Pfizer Australia Pty Ltd	<b>NF</b>	Novo Nordisk Pharmaceuticals Pty. Limited
<b>GA</b>	Galderma Australia Pty Ltd	<b>NG</b>	NEON HEALTHCARE PTY LIMITED
<b>GC</b>	GlaxoSmithKline Australia Pty Ltd	<b>NM</b>	Novartis Pharmaceuticals Australia Pty Limited
<b>GH</b>	Amdipharm Mercury (Australia) Pty Limited	<b>NO</b>	Novo Nordisk Pharmaceuticals Pty. Limited
<b>GI</b>	Gilead Sciences Pty Limited	<b>NP</b>	NICE-PAK PRODUCTS PTY. LTD.
<b>GJ</b>	HALEON AUSTRALIA PTY LTD	<b>NQ</b>	Takeda Pharmaceuticals Australia Pty. Ltd.
<b>GK</b>	GlaxoSmithKline Australia Pty Ltd	<b>NT</b>	Nestle Australia Ltd
<b>GN</b>	Actavis Pty Ltd	<b>NU</b>	Nutricia Australia Pty Limited
<b>GO</b>	Viartis Pty Ltd	<b>NV</b>	Novartis Pharmaceuticals Australia Pty Limited
<b>GQ</b>	Generic Health Pty Ltd	<b>OB</b>	Oral B Laboratories Pty Ltd
<b>GT</b>	Viartis Pty Ltd	<b>OC</b>	Accord Healthcare Pty. Ltd.
<b>GX</b>	Apotex Pty Ltd	<b>OH</b>	Orpharma Pty Ltd
<b>GZ</b>	sanofi-aventis Australia Pty Ltd	<b>OJ</b>	The Trustee for ORSPEC PHARMA UNIT TRUST
<b>HB</b>	Besins Healthcare Australia Pty Ltd	<b>OM</b>	Colgate Oral Care
<b>HQ</b>	Generic Health Pty Ltd	<b>ON</b>	Orion Laboratories Pty. Ltd.
<b>HR</b>	Paul Hartmann Pty Ltd	<b>OQ</b>	Organon Pharma Pty Ltd
<b>HT</b>	BTC Speciality Health Pty Ltd	<b>OS</b>	Otsuka Australia Pharmaceutical Pty. Ltd
<b>HW</b>	HAMELN PHARMA PTY. LTD.	<b>OU</b>	Oraderm Pharmaceuticals Pty Ltd
<b>HX</b>	Sandoz Pty Ltd	<b>OV</b>	Organon Pharma Pty Ltd

<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>OW</b>	Arrow Pharma Pty Ltd	<b>XH</b>	MS Health Pty Ltd
<b>OX</b>	Orion Pharma (Aus) Pty Limited	<b>XI</b>	Alexion Pharmaceuticals Australasia Pty Ltd
<b>PB</b>	Pharmaco (Australia) Limited	<b>XN</b>	Southern XP Pty Ltd
<b>PF</b>	Pfizer Australia Pty Ltd	<b>XO</b>	Echo Therapeutics Pty Ltd
<b>PK</b>	Fresenius Kabi Australia Pty Limited	<b>XT</b>	Arrotex Pharmaceuticals Pty Ltd
<b>PP</b>	Petrus Pharmaceuticals Pty Ltd	<b>XW</b>	Arrotex Pharmaceuticals Pty Ltd
<b>PY</b>	Procter & Gamble Pharmaceuticals Australia Pty Ltd	<b>XY</b>	MAXX PHARMA PTY LTD
<b>QH</b>	Cortex Health Pty Ltd	<b>YG</b>	EUGIA PHARMA (AUSTRALIA) PTY LTD
<b>QS</b>	Sandoz Pty Ltd	<b>YN</b>	Mayne Pharma International Pty Ltd
<b>QY</b>	Pro Pharmaceuticals Group Pty. Ltd.	<b>YO</b>	The Trustee for ORSPEC PHARMA UNIT TRUST
<b>RA</b>	Sun Pharma ANZ Pty Ltd	<b>YT</b>	Mayne Products Pty Ltd
<b>RB</b>	Bio Revive Pty Ltd	<b>ZB</b>	Specialised Therapeutics Pm Pty Ltd
<b>RC</b>	Reckitt Benckiser (Australia) Pty Limited	<b>ZE</b>	Seekwell Pty Ltd
<b>RF</b>	Arrow Pharma Pty Ltd	<b>ZO</b>	Swedish Orphan Biovitrum Pty Ltd
<b>RI</b>	Dr Reddy's Laboratories (Australia) Pty Ltd	<b>ZS</b>	Strides Pharma Science Pty Ltd
<b>RJ</b>	Recordati Rare Diseases Australia Pty. Ltd.	<b>ZU</b>	Seekwell Pty Ltd
<b>RM</b>	Pharmacor Pty Limited		
<b>RN</b>	Sun Pharma ANZ Pty Ltd		
<b>RO</b>	Roche Products Pty Ltd		
<b>RQ</b>	Reach Pharmaceuticals Pty Ltd		
<b>RW</b>	Arrow Pharma Pty Ltd		
<b>RX</b>	Servier Laboratories (Aust.) Pty. Ltd.		
<b>RZ</b>	Dr Reddy's Laboratories (Australia) Pty Ltd		
<b>SA</b>	SciGen (Australia) Pty Limited		
<b>SB</b>	Nutricia Australia Pty Limited		
<b>SE</b>	Servier Laboratories (Aust.) Pty. Ltd.		
<b>SG</b>	Merck Healthcare Pty Ltd		
<b>SI</b>	Sigma Company Limited		
<b>SN</b>	Smith & Nephew Pty Limited		
<b>SS</b>	SSL Australia Pty Ltd		
<b>SW</b>	sanofi-aventis Australia Pty Ltd		
<b>SY</b>	Bayer Australia Ltd		
<b>SZ</b>	Sandoz Pty Ltd		
<b>TB</b>	Teva Pharma Australia Pty Ltd		
<b>TD</b>	STADA Pharmaceuticals Australia Pty Limited		
<b>TF</b>	Te Arai BioFarma Limited		
<b>TG</b>	ANTENGENE (AUS) PTY. LTD.		
<b>TJ</b>	Taiho Pharma Oceania Pty Ltd		
<b>TK</b>	Takeda Pharmaceuticals Australia Pty. Ltd.		
<b>TN</b>	Medtas Pty Ltd		
<b>TQ</b>	Terumo BCT Australia Pty Limited		
<b>TT</b>	Theramex Australia Pty Ltd		
<b>TW</b>	Apotex Pty Ltd		
<b>TX</b>	Apotex Pty Ltd		
<b>TY</b>	Apotex Pty Ltd		
<b>UC</b>	UCB Australia Proprietary Limited		
<b>UG</b>	Urgo Medical Australia Pty Ltd		
<b>UI</b>	PERRIGO AUSTRALIA PTY LIMITED		
<b>UJ</b>	Upjohn Australia Pty Ltd		
<b>UL</b>	Bausch & Lomb (Australia) Pty Ltd		
<b>UM</b>	Unomedical Pty Ltd		
<b>UN</b>	Unilever Australia Limited		
<b>UO</b>	Bausch & Lomb (Australia) Pty Ltd		
<b>UR</b>	Camurus Pty Ltd		
<b>VB</b>	AbbVie Pty Ltd		
<b>VE</b>	AbbVie Pty Ltd		
<b>VF</b>	VitaFlo Australia Pty Limited		
<b>VI</b>	ViiV Healthcare Pty Ltd		
<b>VL</b>	Vifor Pharma Pty Limited		
<b>VO</b>	Avallon Pharmaceuticals Pty Limited		
<b>VQ</b>	Novartis Pharmaceuticals Australia Pty Limited		
<b>VR</b>	Vertex Pharmaceuticals (Australia) Pty. Ltd.		
<b>VZ</b>	Sanofi-aventis Healthcare Pty Ltd		
<b>WA</b>	sanofi-aventis Australia Pty Ltd		
<b>WG</b>	WAGNER PHARMACEUTICALS PTY LTD		
<b>WM</b>	MEDISON PHARMA AUSTRALIA PTY LIMITED		
<b>WZ</b>	Bridgewest Perth Pharma Pty Ltd		
<b>XC</b>	Southern Cross Pharma Pty Ltd		
<b>XE</b>	ACCELAGEN PTY LTD		

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